

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

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| <p>THE UNITED STATES OF AMERICA and THE STATE OF GEORGIA, <i>ex rel.</i> SENTERS,</p> <p><i>Relator,</i></p> <p>v.</p> <p>QUEST DIAGNOSTICS, INC.,</p> <p><i>Defendant.</i></p> | <p>Civil Action File No.:</p> <p>1:10-cv-02202-AT</p> <p>JURY TRIAL DEMANDED</p> |
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FOURTH AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

Relator Barbara Senters, on behalf of the United States of America (“United States”) and the State of Georgia (collectively the “Government”) and herself, brings this action under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, (“FCA”) and the Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq.*, (“Georgia FMCA”) to recover damages, penalties, and other remedies as provided therein. Relator files this Fourth Amended Complaint and Demand for Jury Trial against Quest Diagnostics, Inc. (“Quest”) and alleges as follows:

1. Quest is in the business of selling diagnostic laboratory tests to physicians, multi-provider medical practices and hospitals (collectively, Quest “Clients”) for use in those practitioners’ treatment of patients, including

Government healthcare program beneficiaries. When Quest receives a request from a Client to perform tests for beneficiaries of Medicare or other Government healthcare programs, Quest does the tests and bills the Government for the tests. The Client is not involved in that billing process. While Quest has no obligation to second guess the medical judgment of a Client provider, it does have a very substantial independent obligation not to bill the Government for its tests when those tests are not eligible for reimbursement because they are not medically necessary in the lab billing context as explained below.

2. To be eligible for reimbursement by Medicare, Medicaid and other Government healthcare programs (collectively referred to herein as the “Government”), among other things, each lab test billed to the must be a) ordered by the treating physician, b) for the specific patient, c) to address a specific medical condition, and d) on a specific date. Indeed, Quest is required to expressly certify in each claim it submits to the Government for reimbursement for its tests, that each test is reasonable and necessary. This laboratory billing obligation has been known to Quest since at least 1998, as detailed below, and was, for a period of time, adhered to by Quest until it developed a new means of ordering tests, electronically, which it exploited to the maximum, resulting in enormous damages to the Government.

3. This action is based on Quest knowingly submitting false claims to Medicare, Medicaid, and other Government payors, for laboratory tests that were not eligible for payment because they are not reasonable and necessary/ medically necessary as defined above (hereinafter referred to as not “Reasonable and Necessary”) but which were nevertheless billed to the Government with express false certifications to the contrary in violation of the FCA and the GA FMCA. Quest also made false statements material to Government payment of false claims in violation of the FCA and the GA FMCA.

4. To make it easier for its Clients to order its tests instead of doing business with a Quest competitor, in or around 2002, Quest began developing a proprietary software platform to enable the *electronic* ordering of its tests directly in its Clients’ medical offices instead of using the process of creating a hard copy paper order for each test that accompanied each specimen to a Quest lab.

5. To fraudulently generate more test orders regardless of whether the tests were Reasonable and Necessary (and thus reimbursable by the Government), Quest included in its new software the functionality to allow Quest-employees, specifically, sales representatives who were financially rewarded when Clients ordered more Quest tests, and phlebotomists hired by Quest and placed only in those Client offices that ordered a higher volume of tests, to create customized groupings of Quest tests - panels of tests, known as “ease of order” or “ease of use”

panels of tests - so that when selected by any provider in the Client office, each and every test in the panel would automatically be conducted and billed to the Government with the (false) express certification that each test was Reasonable and Necessary. That certification is required for Government payment. Quest made every customized panel available for selection by any provider in the Client office, regardless of which provider may have been originally involved in its contents. Moreover, the electronic panels did not have expiration dates, so especially when new providers joined the practice and selected an electronic panel, Quest had no idea whether new providers were aware of each Government-reimbursed test that he or she was ordering.

6. Quest's billing software "unbundled" the panel and billed each test individually to the Government with the express certification that each test was Reasonable and Necessary. The Government received individual bills for individual tests from Quest, with no way of knowing that Quest's express certification that each test was 1) ordered by the patient's treating physician, 2) for the specific patient, 3) to treat a specific medical condition, and 4) on a specific date, was false when the Government made its payment decision on every claim submitted by Quest for a test that Quest conducted because it had been included in an ease of order panel. In fact, Quest did not know whether each test was 1)

ordered by the patient's treating physician, 2) for the specific patient, 3) to treat a specific medical condition, and 4) on a specific date.

7. As detailed herein, in enabling its employees to create custom panels electronically directly in Client offices, Quest intentionally and knowingly bypassed its own extensive existing procedures designed and implemented to ensure that its certifications that each test included in a paper-based custom panel, created through the centralized corporate custom panel creation process (as opposed to being created by financially incentivized employees in Client offices directly in Care360) was truthful. The stark contrast between (a) what Quest did to create, use and bill for tests ordered because they had been included in paper panels created through the centralized corporate custom panel creation and use process, versus (b) what it did to create, use and bill for tests ordered because they had been included in electronic panels created in Client offices directly in Care360 demonstrates the fraudulent nature of Quest's conduct and Quest's violations of the False Claims Act and the GA False Medicaid Claims Act.

8. Medical necessity/Reasonable and Necessary status in the lab billing context at issue in this case, should not be confused with *clinical* medical necessity, which refers to a healthcare provider's medical judgement that he or she needs the results of a given diagnostic test to treat his or her patient. Lab billing medical necessity refers to Quest's responsibility pursuant to the rules and

regulations governing the federal and state healthcare programs at issue, to ensure and truthfully expressly certify that each test for which it seeks payment meets four requirements, that it was in fact: 1) ordered by the treating physician, 2) for the specific patient, 3) to treat a specific medical condition, and 4) on a specific date. Quest cannot truthfully certify that mandatory criteria for medical necessity/Reasonable and Necessary status in the lab billing context have been met if it does not know whether in fact those criteria have been met. This false certification of compliance violated the applicable regulations, the FCA, and the GA FMCA, and robbed the Government of the ability to make an informed eligibility and payment decision.

9. Quest encouraged the unsupervised creation of Care360 electronic ease of order panels in Care360 Client offices through training and incentivization of its sales force on a nationwide basis. Quest recognized significant increased revenue from Clients who used Care360 ease of order panels.

10. Care360's ease of order panels¹ are as lucrative for Quest as they are damaging to the Government because they exponentially increase the number of tests conducted and billed to the Government by Quest. The Care360 ease of order

¹ Quest used various names for the electronic customized groupings of tests in Care360 that are at issue in this case, such as "custom profiles." For ease of reference herein, all such groupings of tests in Care360 into Client-selectable panels are referred to as "Care360 ease of order panels."

panels provide a quick and easy testing choice for unwitting, busy healthcare providers serving Government beneficiaries. These providers are engaged in treating patients and are not concerned with whether additional tests recommended by Quest's sales representatives are performed on the same patient sample, so long as they obtain results for the limited number of tests they know their patient needs. Quest's Care360 ease of order panels are the tools of its fraud, which has cost hundreds of millions of dollars to the Government, despite the Government's long-standing efforts to prevent the over-ordering and billing of tests.

11. Quest has successfully "banked" on providers not knowing, or in some cases, not caring, whether they need each of the tests included in a Care360 ease of order panel. They use these panels as a quick and easy testing choice to obtain certain tests, regardless of what other tests, unnecessary tests, may also be in the panel. Quest knows that over-inclusivity of tests is not at the forefront of a provider's mind when treating patients (often under pressure to see as many as possible to drive revenue) and that Care360 ease of order panels save them time. Quest's total awareness of this vulnerability (opportunity) in the test ordering process is readily apparent in, among other things, the safeguards it set up around paper-based custom panels, discussed below.

12. The fact that Medicare only covers tests that are reasonable and necessary for the treatment or diagnosis of an individual patient's illness or injury,

based on his or her medical condition, has not changed since Congress created the program. 42 U.S.C. § 1395y(a)(1)(A). The need for *each test* for *each patient* must be individually assessed and documented in the patient's medical chart, and a laboratory has the burden of producing documentation to support intent to order and the medical necessity of ordered services. 42 C.F.R. § 410.32(a), (d)(2); *see* 42 C.F.R. § 410.1(a)(2) (section 410 implements *inter alia* 42 U.S.C. § 1395y). Nonetheless, Quest sought to, and did, knowingly cause unnecessary and expensive tests to be routinely performed on patients, and falsely billed Medicare and other Government payors, to increase its revenue at the expense of the United States and Georgia, in violation of the FCA and the GA FMCA. This action seeks to recover those funds paid by the Government because of Quest's fraud.

13. Quest had actual knowledge that billing Medicare and other Government payors for medically unnecessary tests by promoting and creating ease of order panels, wherein physicians would order excessive numbers of non-patient-specific tests without individualized assessments of patients' needs, violates federal healthcare program reimbursement rules. Quest, its predecessor entities, as well as other major laboratory companies paid millions of dollars to the Government to settle FCA actions for falsely billing for tests that had been grouped into custom panels. Moreover, Quest's repeated squashing of any attempts to limit the creation and use of its Care360 ease of order panels, described below, demonstrates Quest's

knowledge of the materiality of its false certifications of medical necessity/that each is Reasonable and Necessary.

14. Specifically, in 1998, the Government vigorously pursued and recovered over \$800 million from labs that falsely billed Medicare and other Government payors for medically unnecessary tests which were performed because of their inclusion in automated custom panels, in a multi-agency investigation and prosecution known as “Operation LabScam.” Similar to the schemes alleged in this lawsuit, the marketing and billing schemes employed by those labs promoted the grouping of tests into single automatic panels, encouraging and causing physicians to order every test in a panel, even if the tests were not needed to diagnose or treat the patient. The labs would then bill the Government separately for each test purportedly “ordered” by the physician, including tests that the labs knew would not be needed to diagnose or treat the patient. The Government dubbed the paper lab test requisition/order form with boxes to check to select panels and automatically order every (unnamed) test in each of the panels, as the “instrument of the crime.” The “instrument of the crime” in this lawsuit is the availability of selecting a Care360 ease of order panel with the click of a button, thereby generating a request that Quest conduct and bill every single test in the panel. Quest knew what was required to truthfully certify medical necessity when it billed for tests done because they had been included in a custom panel selected on a

paper test requisition form. It had corporate procedures in place across the country designed to ensure that Quest could truthfully certify the medical necessity of each test billed in a paper-driven custom panel. By contrast, in creating Care360 and the ability to create electronic ease of order panels in customers' offices, Quest knowingly flouted all of those procedures and made it impossible to truthfully certify medical necessity of each test in said panels. As detailed below, when Relator raised a comparison between the paper-based custom panels at issue in Operation LabScam and Quest's implementation of Care360 ease of order panels, the highest levels of Quest management shut her off from communicating about it and removed her from further dialogue about the legitimacy of billing for tests included in the Care360 ease of order panels.

15. As part of Operation LabScam, Quest's predecessor, SmithKline Beecham Clinical Laboratories, ("SBCL") was ordered to pay \$325 million for falsely certifying medical necessity and filing false claims with the Government for providing custom profiles (containing groups of tests not needed or specifically and knowingly ordered by the physician) to treating physicians to increase profits per transaction. In addition to the monetary settlement and to avoid exclusion from participation in Medicare, Medicaid, or other Government programs, SBCL also entered an extensive corporate integrity agreement ("CIA") with the Government that was designed to prevent the fraudulent conduct from occurring again. In 1999,

Quest acquired SBCL and became subject to its CIA.

16. Having acquired two of the defendants in Operation LabScam shortly after its conclusion and being subject to SBCL's CIA, Quest knew that falsely certifying medical necessity and filing false claims with the Government for providing custom panels containing tests that were not needed or specifically and knowingly ordered by the physician was fraudulent. In fact, in its compliance training, Quest specifically instructed that the Government's enforcement initiative in Operation LabScam was based on the defendant labs' having their clients order tests in conveniently named customized groupings or panels of tests rather than ordering them individually. But as Relator learned, Quest regarded Operation LabScam as an example of how to maximize revenue and defraud the Government via using customized panels of tests, and implemented the same scheme, substituting the pre-printed, hard-copy script pads on which Clients selected panels of tests with modern-day electronic selections of customized panels as the tool of the fraud to introduce a new era of LabScam.

17. In 1998, Quest paid the Government \$6.89 million for filing false claims for tests that had incomplete or missing physician order forms. Quest acknowledged that the practice of performing and billing for tests without appropriate prior or subsequent physician authorization is in violation of federal regulations. As part of the settlement, Quest amended its prior CIA, referenced

above, and actually created a compliance training video for all new employees acknowledging as fraudulent the very scheme alleged by Relator in this lawsuit.

18. In April 2009, as part of a \$302 million settlement with the U.S. Department of Justice and other federal Government agencies to resolve False Claims Act allegations relating to tests that allegedly provided inaccurate and unreliable results, Quest entered into a five-year Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General, effective from April 14, 2009 through August 8, 2014. The CIA required Quest's Board to retain an expert to review how well compliance concerns were communicated to senior management, among other things, and threatened substantial monetary penalties as well as suspension or termination from participating in certain federal healthcare programs for noncompliance.

19. As detailed below, at the very time that it was developing Care360 and its ease of order panels, Quest knew that billing Government payors for tests that Quest did not know were Reasonable and Necessary required Quest to submit a false express certification to the contrary that robbed the Government of the ability to make an informed eligibility and payment decision, thus violating federal healthcare program rules, the FCA and the GA FMCA. Relator warned Quest that Defendants' schemes were illegal, but Quest nonetheless pressured its employees into participating in these schemes by fostering a culture of greed and intense sales

pressure.

20. Relator also warned that the way in which Care360 Panels were created and used to generate tests billed to the Government gave rise to a reporting obligation under the April 2009 CIA, but was rebuffed by upper management in that regard and no report was made.

21. Quest chose profit over compliance and encouraged its sales representatives with financial incentives to create as many ease of order panels as possible. By its fraudulent conduct in designing, creating, and implementing Care360 ease of order panels across the United States, Quest wrote a blank check to itself from the Government, including the Medicare Trust Fund, the United States Treasury, and the coffers of the State of Georgia.

22. Quest knowingly submitted hundreds of thousands of false and fraudulent claims to Medicare, Medicaid, and other Government payors as described herein, resulting in hundreds of millions of dollars of Government payments that would not otherwise have been paid.

23. The Government could not (and would not) have lawfully paid Quest's false claims had it known of Quest's violations of Medicare, Medicaid, and other federal and state regulations because such payment is statutorily prohibited. *See* 42 U.S.C. § 1395y. As a result, as detailed below, Quest's false certifications of medical necessity were material to the Government's decisions to pay Quest's false

claims.

24. Relator has insider knowledge of Quest's fraudulent conduct and of Quest's regularly billing the Government for tests conducted because of their prior inclusion in an ease of order panel. Relator personally looked at thousands of actual claims submitted to Medicare or Medicaid for tests submitted because they had been included in Care360 ease of order panels. She did so as part of an investigation she undertook in 2009 (detailed below) in which she identified Care 360 ease of order panels used by Clients, and compared on a patient by patient basis, a scanned copy of the actual script pad or order form on which the provider selected the panel to the Care360 test requisition and then worked with the Quest billing department to pull the actual Quest claims to a Government payor for each test in the panel. Relator undertook this process for months and was trained by several different Billing Department employees and supervisors to pull claims data by payor, patient name and/or Client account code. She became so adept at doing so that she was able to pull the claims herself directly from Quest's billing software. Representative examples of actual false claims submitted by Quest to Medicare are described herein with copies of the documents showing the fraudulent scheme and the false claims.

25. The false claims at issue in this case request payment for lab services that Quest did not and could not know were "Reasonable and Necessary" and were

thus eligible for payment. Quest's certification of same is material to, and a precondition of, the Government's decision to pay each of Quest's claims. 42 U.S.C. § 1395y(a)(1)(A).

PARTIES

26. Relator Barbara Senters ("Relator"), a former resident of the State of Georgia, was hired by Quest in August 2005 in Lexington, Kentucky as a Senior Human Resource Generalist. In August 2006, she transferred to Atlanta, Georgia the Southeastern Business Unit's ("SE BU's") headquarters in that same position. In late 2007, she was asked to undertake the responsibilities of the BU Compliance Officer, serving Georgia, North Carolina, South Carolina, Tennessee and Alabama. In May 2008, she was officially promoted into that position. She left Quest employment in October 2010 after fighting to no avail to stop Quest's submission of false claims to Government payors.

27. As Compliance Officer for the SE Business Unit, Ms. Senters reported to the Managing Director of the SE BU, Jeff Broka. As a BU Compliance Officer, Ms. Senters had a dotted line report to the Quest Regional Compliance Officer for the Central Division, M.H., one of three regional compliance officers in the country. M.H. had responsibility for eight (8) business unit compliance officers, including the SE BU headquartered in Atlanta. Also in Relator's Compliance Department chain of command was Quest's Director of Compliance Operations,

Carl Landorno, Quest's Director of Compliance Audit, Product Offerings and Refunds, Lynn Wiser, and finally, Quest's Vice President of Compliance, Timothy Sharpe. Quest also had a Compliance Director of Sales and Marketing, J.H., during Ms. Senters tenure, who was outside of the Compliance Operations chain of command under Carl Landorno, but who also eventually reported up to VP Timothy Sharpe.

28. Due to the centralized nature of the Compliance Department under VP Sharpe, Relator regularly worked with all Compliance personnel around the country. Compliance held regular regional and nationwide telephonic meetings and regularly communicated issues throughout the Department nationwide via email and hard copy materials. Ms. Senters also regularly worked with Quest's in-house Compliance attorney, Kenney Johnson.

29. As part of her regular job duties, Relator was privy to Quest's nationwide compliance issues and in 2009 learned that failure to comply with applicable laws and policies in test ordering was the #2 compliance issue across the country in 2008 and in 2009. Also, as part of her job duties, Relator had access to the Quest Intranet and the actual "Care360 Project Pipeline" in which users of the software discussed improvements needed and functionality of the System as it was being developed by Quest, including the creation of ease of order panels.

30. As detailed below, Relator learned the details of Quest's design, and implementation of ease of order panels in Care360 and that Quest acted with full knowledge that it was bypassing the procedures in place designed to prevent false claims from the use of custom panels created via the sanctioned, centralized corporate custom panel creation and use process, instead encouraging the lucrative submission of false claims from the creation and use of electronic ease of order panels created directly in Client offices in Care360.

31. One of her central job duties was to ensure that Quest was billing Government payors only for tests that were eligible for reimbursement. Her official, written job duties in Quest's Job Description for "Unit Compliance Officer" dated March 2005 and in place throughout her tenure in the position included the duty to "Ensure operational compliance with payor requirements through interaction with local Business Unit billing practices...." She was also tasked with "Ensur[ing] that proper procedures are in place to file, store and retrieve medical and billing records in an orderly, legible, and accurate manner." In practice, most of her job dealt with trying to ensure proper billing to Government payors.

32. Relator has direct, personal knowledge of the matters alleged herein, and prior to filing this action, disclosed substantially all material evidence and

information she possesses to the United States, pursuant to 31 U.S.C. § 3730(b)(2), and to the State of Georgia, pursuant to O.C.G.A. § 49-4-168.2.

33. Quest is incorporated under the laws of the State of Delaware, with its principal place of business currently located at 500 Plaza Drive, Secaucus, New Jersey 07094. Quest may be served with process through its designated agent for service, Corporation Service Company, at 251 Little Falls Drive, Wilmington, Delaware 19808. At all times relevant hereto, Quest conducts business in all fifty states, including Georgia. Quest performs medical diagnostic testing and operates, controls, and owns a series of laboratory facilities and associated subsidiary companies throughout the country that obtain payment for their services through participation in Medicare, Medicaid, and other Government-funded healthcare programs.

34. Quest is the nation's largest provider of clinical laboratory testing, annually doing testing on one in three adult Americans for half the physicians and hospitals in the United States. In 2016, Quest's market share for outreach laboratory services dominated the competition at 63% of the total clinical testing industry. Fueled by Medicare, Medicaid, and other Government program funding, Quest generated net revenues of \$7.7 Billion, \$7.5 Billion, and \$7.7 Billion in 2017, 2018, and 2019, respectively.

35. Quest prioritized the Sales Department and separated it from the general management structure of the corporation: The Physician Sales Directors and the Hospital Sales Directors did not report to the Managing Directors of the business units, but instead to the Regional Sales Directors and the Corporate Sales Director, bypassing the Business Unit Managing Directors such as Jeff Broka who, for example, had to certify to the Government that there were no reportable issues in his SE BU under the CIAs.

36. In 2020, Quest had 43,000 employees nationwide, 1,500 of whom were sales professionals. The Sales Department's role is to increase revenue by promoting Quest services to both existing and potential clients. Such activities include making sales calls to acquire new business, making sales calls to promote new services, testing, and technologies (Care360, electronic health record, and e-prescribe), including up-selling existing tests to physicians and satisfying requests of clients. The sales force's compensation is primarily based upon commissions. These sales commissions are based upon performance versus their quota and the revenue per client in the book of business they maintain or acquire.

37. The commission is designed to achieve profitable business growth by increasing the number of accounts and increasing the revenue from each account. The incentive "mix" depends upon the Sales position held by the individual that in some positions have a lower base salary with higher variable commission, and vice

versa. The position of Account Sales Representative ("Sales Reps") involves significant contact with Clients and is involved with the creation of Care360 ease of order panels peer their training by Quest.

38. Sales Reps are highly scrutinized based on meeting their quotas and face performance management up to and including termination based on their performance, which is measured primarily by net revenue generated by the Sales Rep's book of business.

39. In 2010, of Quest's 43,000 employees, 8,000 of them were phlebotomists. Quest provides phlebotomists to those Clients that achieve a certain volume of tests ordered (potential profitability to Quest). The phlebotomists actually work in the Client offices and are paid by Quest and not by the Client. Thus, a Quest employee is on-site and available to immediately take test orders from the Client.

40. Quest IOPs are responsible for receiving and ensuring the completion of orders of tests/requisition orders from Clients and drawing the specimens for such orders. When a physician wants to order a particular laboratory test, the physician, or his or her office personnel contacts a Quest phlebotomist who handles it from there. Phlebotomists who do not work in a Client office work in Quest testing centers known as Patient Services Centers ("PSCs").

41. Phlebotomists are eligible for bonuses based on a "goal sharing" program. This program recognizes and rewards employees for the results of their BU through individual and team contributions based on annually established financial and other performance objectives. These payments range between 0-6% of employee's annual salary, which is based on the overall performance of the BU and the IOP's personal performance.

42. At all times relevant hereto, Quest acted through its agents and employees within the scope of their agency and employment. All acts or omissions alleged herein were at the direction of, under the control of, under the management of, ratified by, or the result of policies set forth by Quest.

JURISDICTION AND VENUE

43. This Court has subject-matter jurisdiction over this action pursuant to 31 U.S.C. § 3730 and 28 U.S.C. §§ 1331, and 1345.

44. The Court may exercise personal jurisdiction over Defendants under 31 U.S.C. § 3732(a) because Defendants transact or transacted business in this district.

45. Venue is proper in this district pursuant to 31 U.S.C. § 3732 because Defendants transact or transacted business in this district.

FEDERALLY FUNDED HEALTHCARE PROGRAMS

46. At all times relevant to this Complaint, Quest was enrolled in, and sought and received reimbursement from, Medicare, Medicaid, and other Government-funded programs including, but not limited to, the Veterans Administration, the Federal Employees Health Benefits Program, CHAMPUS/TRICARE, and CHAMPVA.

The Medicare Program

47. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, establishes the Health Insurance for the Aged and Disabled Program, popularly known as the Medicare Program, which is administered through the Centers for Medicare and Medicaid Services (“CMS”).

48. Medicare is comprised of Parts A, B, C, and D. Part B is medical insurance that authorizes payment of federal funds for laboratory diagnostic services. *See* 42 U.S.C. § 1395k; 42 C.F.R. § 410.10. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the federal treasury. CMS contracts with private insurance companies to administer, process, and pay Part B claims.

49. HHS has overall responsibility for the administration of Medicare. Within HHS, the responsibility for the administration of Medicare has been delegated to CMS.

50. Reimbursement for Medicare Part B claims is made by the United States through CMS, which contracts with fiscal intermediaries, also known as Medicare Administrative Contractors (“MACs”), acting on its behalf to administer and pay Medicare Part B claims from the Medicare Trust Fund and perform administrative functions on a regional level. *See* 42 U.S.C. § 1395(u); *see also*, 42 C.F.R. § 421.5(b).

51. Under Medicare Part C, Medicare beneficiaries may opt out of traditional Medicare and instead enroll in Medicare Advantage Plans to receive healthcare services managed by those Plans but funded by the Government. *See* 42 U.S.C. §§ 1395w-21 to 1395w-28. MA Plans are run by private insurers known as MA Organizations (“MAOs”). *See* 42 C.F.R. §§ 422.2, 422.503(b)(2).

52. Under Medicare Part C, MAOs contract with CMS to provide services to people who are eligible for Medicare. *See* 42 U.S.C. §§ 1395w-21-1395w-28. MAOs provide coverage that is at least equivalent to Part B.

53. Many MAOs contract with hospital networks, physician groups, and other providers to furnish healthcare services under the MA Plans.

54. As a Medicare provider, Quest was obligated to understand and certify its compliance with all applicable Medicare laws, regulations, and program instructions as a condition of participation in Part B and as a condition of payment of Medicare reimbursements.

55. Medicare providers like Quest are reimbursed for covered services based on their submission of an electronic or hard copy claim form called the CMS Form 1500 Health Insurance Claim Form.

56. When submitting claims to Medicare, providers expressly certify on CMS Form 1500, *inter alia*, that (a) the services rendered are “medically indicated and necessary for the health of the patient;” (b) the information on the claim form is “true, accurate and complete;” and (c) the provider understands that “payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal and State laws.” After a February 2012 revision to CMS Form 1500, providers further expressly certify that their claims comply “with all applicable Medicare . . . laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law).”

57. CMS Form 1500 also requires providers to acknowledge that: “Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.”

58. Because it is not feasible for Medicare personnel to review every patient’s medical records for the millions of claims for payments it receives from

providers, the Program relies on providers to comply with Medicare requirements and trusts providers to submit truthful and accurate certifications and claims.

59. Generally, once a provider submits CMS Form 1500, or its electronic equivalent, to Medicare, the claim is paid directly to the provider, in reliance on the provider's certifications, without any review of supporting documentation, including medical records.

60. In order to receive reimbursement from Medicare, a lab test must be "reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). In addition, Medicare will make "[n]o payment . . . unless there has been furnished such information as may be necessary in order to determine the amounts due such provider..." 42 U.S.C. § 1395l(e). It is a laboratory's responsibility to demonstrate that all tests are Reasonable and Necessary for payment purposes.

61. In addition, Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

62. Before participating in the Medicare Program, providers such as Quest are required to certify compliance with Medicare's rules and regulations.

Thereafter, each time the provider submits a claim for payment, it is required to recertify its continued compliance.

63. To participate in the Medicare program as a new enrollee, clinical laboratories such as Quest must submit a Medicare Enrollment Application, Form CMS-855B, in order to bill or receive funds from Medicare. *See* CMS-855B, Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers. Enrolled providers of medical services to Medicare beneficiaries are eligible for Government reimbursement for covered medical services and must agree to abide by the rules, regulations, policies, and procedures governing claims for payment in order to receive such reimbursement.

64. CMS Form 855-B requires, among other things, signatories to certify:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier...I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

* * *

I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

65. The enrollment application “explains the penalties for deliberately falsifying information in [the] application to gain or maintain enrollment in the

Medicare program.” In addition to criminal penalties, the enrollment application informs provider applicants of the following:

The Civil False Claims Act, 31 U.S.C. § 3729, imposes civil liability, in part, on any person who:

- a) knowingly presents, or causes to be presented, to an officer or any employee of the United States Government a false or fraudulent claim for payment or approval;
- b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; or
- c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

The Act imposes a civil penalty of \$5,000 to \$10,000 per violation, plus three times the amount of damages sustained by the Government.

* * *

Section 1128A(a)(1) of the Social Security Act imposes civil liability, in part, on any person (including an organization, agency or other entity) that knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency...a claim...that the Secretary determines is for a medical or other item or service that the person knows or should know:

- a) was not provided as claimed; and/or
- b) the claim is false or fraudulent.

This provision authorizes a civil monetary penalty of up to \$10,000 for each item or service, an assessment of up to three times the amount claimed, and exclusion from participation in the Medicare program and State health care programs.

* * *

The Government may assert common law claims such as “common law fraud,” “money paid by mistake,” and “unjust enrichment.” Remedies include compensatory and punitive damages, restitution, and recovery of the amount of the unjust profit.

66. As part of the enrollment application process, an authorized official with legal authority to enroll the provider in the Medicare Program and “to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program” must execute a Certification Statement, which legally and financially “binds the [provider] to all of the requirements listed in the Certification Statement and acknowledges that the [provider] may be denied entry to or revoked from the Medicare program if any requirements are not met.”

67. Authorized officials for Quest signed the certification statements in Form CMS-855B, indicating that they understood that the laboratory was required to comply with Medicare laws, regulations, and program instructions in order to bill or receive funds from Medicare.

68. The enrollment application sets forth the following, inter alia, “additional requirements that the [provider] must meet and maintain in order to bill the Medicare [P]rogram” and which the provider must certify and attest to having read and understood:

I have read and understand the Penalties for Falsifying Information, as printed in this application. I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare, or any deliberate alteration of any text on this application form,

may be punished by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment.

* * *

I agree to abide by the Medicare laws, regulations and program instructions that apply to this [provider]...I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare. I agree that any existing or future overpayment made to the [provider] by the Medicare program may be recouped by Medicare through the withholding of future payments.

* * *

I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

69. After its initial certification, a provider has an ongoing duty to “immediately” notify Medicare “if any information furnished on the application is not true, correct, or complete:”

[A]n authorized official, by his/her signature, agrees to notify the Medicare fee-for-service contractor of any future changes to the information contained in this form, after the [provider] is enrolled in Medicare, in accordance with the timeframes established in 42 C.F.R. 424.516.

70. In addition to the initial and ongoing certifications, each time a provider submits a claim, electronically or otherwise, the submission must state, in boldface type, immediately preceding the provider's signature:

(1) “This is to certify that the foregoing information is true, accurate, and complete.”

(2) “I understand that payment of this claim will be from Federal and State funds, and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws.”

42 C.F.R. § 455.18(a).

71. The claim form used by Quest to bill the Government is the CMS Form 1500 (or its electronic equivalent, known as the 837P format), in which Quest certifies that:

- 1) the information on this form is true, accurate and complete;
- 2) I have familiarized myself with all applicable laws, regulations, and program instructions...;
- 3) I have provided or will provide sufficient information required to allow the [G]overnment to make an informed eligibility and payment decision;
- 4) this claim...complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment...;
- [and] 5) the services on this form were medically necessary...

CMS-1500; *see* 42 C.F.R. § 424.32.

72. CMS Form 1500 also requires the provider to certify its understanding “that payment and satisfaction of [the] claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.” *Id.*

73. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. *See Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984).

74. Healthcare providers are prohibited from knowingly presenting or causing to be presented claims that represent a pattern of items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent. 42 U.S.C 1320a-7a(a)(1); 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).

75. At all relevant times, Quest was enrolled as a provider in Medicare and billed Medicare under Part B, which covers certain medical services, including clinical laboratory test services, furnished by physicians and other providers and suppliers, by submitting claims for reimbursement to the MAC.

The Medicaid Program

76. The Medicaid Program was created in 1965 when Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program to aid participating states in providing medical services to the financially needy, aged, blind, or disabled, and families with dependent children. *See* 42 U.S.C. §§ 1396-96w. Medicaid is funded by both federal and state Governments, with the federal contribution computed separately for each state. *See* 42 U.S.C. §§ 1396b, 1396d(b).

77. Medicaid serves as the nation's primary source of health insurance coverage for low-income populations, providing coverage to over sixty-five million people. All states, the District of Columbia, and the U.S. territories have

Medicaid programs.

78. Medicaid is administered by CMS at the federal level and by state agencies in each of the 50 participating states at the state level. The states establish eligibility standards, the scope and types of services covered, and the rate of payment, as set forth by the federal Medicaid statute. 42 U.S.C. § 1396a.

79. The federal Government pays a share of each state's Medicaid expenditures. The federal medical assistance percentage ("FMAP") calculation determines the amount of federal reimbursement for each state's Medicaid expenditures. FMAP is calculated using the per capita income amounts of the state relative to total U.S. per capita income.

80. The FMAP formula is designed so that the federal Government pays a larger portion of Medicaid costs in states with lower per capita incomes relative to the national average.

81. At all times relevant to this Complaint, the United States provided funds to the states through the Medicaid Program pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.* As a prerequisite to enrollment as a provider in the Medicaid Program, participants are required to enter into provider agreements and agree to comply with federal and state provider participation requirements and the rules, regulations, policies, and procedures governing claims for payment under the provisions of Title XIX of the Social Security Act as a

condition of federal and state funding.

82. Medicaid programs require enrolled providers, such as Quest, to certify compliance with all federal and state statutes and regulations in order to receive payment from Medicaid.

83. At all relevant times, Quest was enrolled as a provider in Medicaid and submitted thousands of false claims for payment to the Medicaid program, including the Georgia Medicaid program.

84. As one regulatory facet of the State Plan, CMS requires that all state Medicaid programs, including Georgia, cover “laboratory services,” which include only “professional and technical laboratory...services” that are “ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts with the scope of his practice as defined by State law or ordered by a physician but provided by a referral laboratory.” 42 C.F.R. §§ 441.17, 440.30(a).

85. The Georgia Department of Community Health (“DCH”) is responsible for the administration and supervision of the Medicaid program. O.C.G.A. §§ 49-4-140 *et seq.* grants the DCH the authority “to establish such rules and regulations as may be necessary or desirable in order to execute the state plan and to receive the maximum amount of federal financial participation available in expenditures made pursuant to the state plan[.]” O.C.G.A. § 49-4-142(a). Georgia regulations authorize and require that the Department “publish the terms and

conditions for receipt of medical assistance in Policies and Procedures manuals for each of the categories of services authorized under the State Plan.” Ga. Comp. R. & Regs. R. 350-1-.02(3). These manuals are disseminated to providers enrolled in the applicable category of service, and amendments thereto are effective “as specified by the Department at the time of dissemination.” *Id.* Thus, the DCH sets the rules for the provision of medical services to Georgia Medicaid recipients, the circumstances in which providers can become enrolled in Georgia Medicaid, and how Georgia Medicaid reimburses providers for these claims.

86. In addition to administering the Fee For Service (“FFS”) Medicaid program directly on behalf of such recipients, the DCH has also partially delegated administration to Care Management Organizations (“CMOs”), which administer health plans and process and pay Medicaid claims. Effective June 1, 2006, the State of Georgia implemented Georgia Families (“GF”), a managed care program through which health care services are delivered to members of Medicaid and PeachCare for Kids. At all times relevant to the Complaint, the managed care portion of Georgia Medicaid was provided by the Amerigroup, Peach State, and WellCare plans. Claims submitted to CMOs by providers are paid on a claim-by-claim basis by the CMO, the cost of which is reimbursed to the CMO by the State on a per-patient capitated basis.

87. At all times relevant to the Complaint, the Georgia Medicaid program

has required every provider who seeks payment to first enroll in the program.

88. At all times relevant to the Complaint, Quest was an enrolled Medicaid provider. Therefore, Quest submitted the following agreements described below.

89. As part of the enrollment, all Georgia Medicaid providers must enter into an agreement with the State called a “Statement of Participation,” commonly referred to as a provider agreement. Among the express understandings in the Provider Agreement are:

Provider shall comply with all of the Department’s requirements applicable to the category(ies) of service in which Provider participates under this Statement of Participation, including Part I, Part II, and the applicable Part III manuals. ¶2(A).

Claims Submissions: Certification of Claims. Provider shall submit claims for Covered Services rendered to eligible Medicaid recipients in the form and format designated by the Department. For each claim submitted by or on behalf of Provider, Provider shall certify each claim for truth, accuracy and completeness... ¶2(B)(4)(A).

Provider shall maintain in an orderly manner and ensure the confidentiality of all original source documents, medical records, identifying recipient data, and any copies thereof, as may be necessary to fully substantiate the nature and extent of all services provided. ¶2(B)(4)(B).

Provider shall render Covered Services, as defined in the Department’s Policies and Procedures manuals, to eligible Medicaid recipients that are medically necessary as defined by the Department...By submitting claims for reimbursement, Provider certifies that Covered Services were rendered in the amount, duration, scope and frequency indicated on the claims. ¶2(B)(4)(C).

Payment shall be made in conformity with the provisions of the Medicaid program, applicable federal and state laws, rules and regulations promulgated by the U.S. Department of Health and Human Services and the State of Georgia, and the Department's Policies and Procedures manuals in effect on the date the service was rendered...Provider agrees that the Department shall not reimburse any claim, or portion thereof, for services rendered...for which federal financial participation is not available. ¶2(B)(4)(D).

Provider acknowledges that payment of claims submitted by or on behalf of Provider will be from federal and state funds, and the Department may withhold, recoup, or recover payments as a result of Provider's failure to abide by the Department's requirements. ¶2(B)(4).

Id. Therefore, providers must certify their understanding that Georgia Medicaid may withhold payment for claims submitted in violation with the Policies and Procedures manuals, incomplete or untruthful claims, unsubstantiated claims, inaccurate claims, claims submitted in violation of law, and claims submitted for which federal financial participation is not available.

90. Further, all Georgia Medicaid providers wishing to submit claims electronically rather than on paper must complete an Electronic Funds Transfer Agreement. Receiving payment for claims requires the following:

Legal Compliance. Provider shall abide by all federal and state laws governing the Medicaid program.

Provider further acknowledges and agrees that only Payees who have agreed in writing to: 1) comply with all Department policies regarding the payment of medical assistance; and 2) be subject to the recoupment policies outlined in the Provider's Statement of Participation and as set forth in the Power of Attorney for Electronic Claims Submission, shall be deemed acceptable Payees.

Provider understands that payment will be from federal and state funds and that any falsification, or concealment of a material fact, may be prosecuted under federal and state laws.

Id.

91. To act as a billing service for an enrolled provider's medical assistance claims submitted electronically, the authorized agent must complete a Power of Attorney for Electronic Claims Submission. Quest signed this form, certifying:

[T]hat all information contained on and submitted by Computer Media Input is true, accurate, and complete, and that to the best of my knowledge, information and belief, the services for which medical assistance was sought, in fact, have been rendered by Provider as claimed. Furthermore, I understand and acknowledge that the Department will rely on this certification in the payment of medical assistance, which payment will be made from State and Federal funds, and that the submission of any false claims, information, or documents or the concealment of any material facts is a crime under Federal and State laws.

Provider understands that the granting of this Power of Attorney in no way limits or discharges the ultimate responsibility and liability of Provider for the truthfulness, completeness and accuracy of any and all medical assistance claims submitted by the appointed billing service, and in no way forecloses the application of penalties that may be assessed under the False Claims Act and other applicable federal and state laws.

Id. As a result, providers and their power of attorney certify and understand that Georgia Medicaid relies upon their truthful representations of compliance with State and Federal laws, and reminds providers that failure to do so is punishable under law.

92. In Georgia, providers participating in the Medicaid program submit claims for laboratory services rendered on behalf of Medicaid beneficiaries to the DCH for payment either directly or through a State designee, such as a fiscal intermediary, or a contractor CMO.

93. As part of its oversight of the Medicaid program, the DCH promulgates Policy Manuals that are applicable to enrolled providers. As noted above, each provider expressly certifies compliance with these manuals in the Statement of Participation (*i.e.*, providers must agree to “comply with all of the Department’s requirements applicable to the category(ies) of service in which Provider participates..., including Part I, Part II, and the applicable Part III Manuals”). Providers also acknowledge that payment for submitted claims is contingent upon their “compl[iance] with all Department policies regarding the payment of medical assistance.”

94. At all times relevant to the Complaint, Quest was enrolled in the Independent Laboratory Services program and therefore subject to the Part I Medicaid/PeachCare for Kids Manual and the Part II Independent Laboratory Manual.

95. The Part I manual, “[a]long with the Statement of Participation, [] encompasses the terms and conditions for receipt of reimbursement.” Georgia Department of Community Health (DCH), Part I Policies and Procedures for

Medicaid/PeachCare for Kids, at “Preface.” The Part I manual reiterates and reemphasizes the importance Georgia places on compliance and further spells out the specific conditions it places on providers submitting claims. For example, under the Part I manual, each enrolled provider must:

[C]omply with all State and Federal laws and regulations related to furnishing Medicaid/PeachCare for Kids services; *Id.* at R. 106(B), p. I-11.

[N]ot engage in any act or omission that constitutes or results in over utilization of services; *Id.* at R. 106(G), p. I-12.

[B]ill the Division for only those covered services that are medically necessary and within accepted professional standards of practice; *Id.* at R. 106(K), p. I-12.

96. As defined by the Part I manual, “Medically necessary, medical necessity or medically unnecessary and appropriate” means:

. . . medical services or equipment based upon generally accepted medical practices in light of conditions at the time of treatment which is (a) appropriate and consistent with the diagnosis of the treating physician and the omission of which could adversely affect the eligible member’s medical condition, (b) compatible with the standards of acceptable medical practice in the United States, (c) provided in a safe, appropriate and cost-effective setting given the nature of the diagnosis and the severity of the symptoms, (d) not provided solely for the convenience of the member or the convenience of the health care provider or hospital, (e) not primarily custodial care unless custodial care is a covered service or benefit under the member’s evidence of coverage, and (f) there must be no other effective and more conservative or substantially less costly treatment, service and setting available.

Id. at “Definitions,” No. 24 at p. Definitions-4.

97. Thus, the Georgia Medicaid/PeachCare for Kids Part I Policy Manual expressly prohibits conduct that encourages over-utilization of testing and other services and requires the submission of only those claims that are medically necessary.

98. These rules apply to every claim an enrolled provider submits. Enrolled providers must “[a]ccept responsibility for every claim submitted to the Division that bears the provider’s name or Medicaid/PeachCare for Kids provider number.” *Id.* at R. 106(L), p. I-12.

99. For each claim submitted, the provider agrees to “[m]aintain such written records...as necessary to disclose fully the extent of services provided and the medical necessity for the provision of such services, for a minimum of five (5) years after the date of service.” *Id.* at R. 106(R), p. I-13.

100. Providers like Quest understand and are on notice that failure to follow any of these rule manual provisions may result in withholding of payment yet to be disbursed or the recoupment of monies already distributed. Under the Part I manual, “[t]he Division may deny any portion or all of a provider’s claim for reimbursement” if, among other reasons, “[t]he services provided have been determined to be medically unnecessary or of substandard quality[.]” *Id.* at “Denial of Reimbursement,” R. 405(D), p. IV-12.

101. The Division may also “deny any portion or all of a provider’s claim for reimbursement” as a result of “[n]oncompliance with any of the Division’s applicable policies or procedures.” *Id.* Those applicable policies and procedures are found in the applicable provider manuals.

102. Thus, providers that enroll in the Georgia Medicaid program know that compliance with provisions 106(B), (E), (G), (J), (K), and (R) are material to Georgia Medicaid’s decision to reimburse claims.

The TRICARE Program

103. TRICARE (formerly CHAMPUS) is a triple option benefit plan established by Congress and funded through federal appropriations and allocated as part of the National Defense Authorizations Act. TRICARE was established by statute, 10 U.S.C. §§ 1071-1110, and provides health care benefits to eligible beneficiaries, which include, among others, active-duty service members, retired service members, and their dependents.

104. TRICARE covers diagnostic testing and services similar to Medicare. The regulatory authority implementing the TRICARE program provides reimbursement to health care providers applying the same reimbursement scheme and coding parameters that the Medicare program applies. 10 U.S.C. §§1079(G)(2) (institutional providers).

105. TRICARE, like Medicare, pays only for “medically necessary

services and supplies required in the diagnosis and treatment of illness or injury.”

32 C.F.R. § 199.4(a)(1)(i).

106. TRICARE prohibits practices such as submitting claims for services that are not medically necessary, consistently furnishing medical services that do not meet accepted standards of care, and failing to maintain adequate medical records. 32 C.F.R. §§ 199.9(b)(3)(b)(5). TRICARE considers “[b]illings or CHAMPUS claims which involve flagrant and persistent overutilization of services without proper regard for results, the patient's ailments, condition, medical needs, or the physician’s orders” to be fraud. 32 C.F.R. § 199.9(c)(3). Such practices are deemed abusive and cause financial loss to the United States. 32 C.F.R. §§ 199.9(b).

107. At all relevant times, Quest was enrolled as a provider in TRICARE and submitted thousands of false claims for payment to TRICARE.

The Federal Employees Health Benefits Program (“FEHBP”)

108. The FEHBP is a federally funded health care program established by Congress in 1959, pursuant to the Federal Employees Health Benefits Act. 5 U.S.C. §§ 8901 *et seq.* The Office of Personnel Management (“OPM”) administers this program and contracts with various health insurance carriers to provide services to FEHBP members. *Id.* at §§ 8902, 8909(a).

109. Monies for the FEHBP are maintained in the Employees Benefits

Fund (“Treasury Fund”), which OPM administers. *Id.* at § 8909(a).

110. The Treasury Fund, which the United States Treasury holds and invests, is the source of all relevant payments to the insurance carriers for services rendered to members. *Id.* § 8909.

111. Benefits under the FEHBP program are payable only when medically necessary to prevent, diagnose, or treat an illness, disease, injury, or condition. *See* 5 U.S.C. § 8902a(c)(4) (billing for medically unnecessary services a basis for debarment). During the relevant time period, the benefit plans for FEHBP insurance carriers Blue Cross and Blue Shield, Government Employees Hospital Association, Inc., and Mail Handlers Benefit Plan specifically provided that they did not cover services, drugs, or supplies that are not medically necessary. *See, e.g.,* 2015 Blue Cross and Blue Shield Service Benefit Plan, at 148.

112. At all relevant times, Quest was enrolled as a provider in FEHBP plans and submitted thousands of false claims for payment to the FEHBP insurance carriers.

**ELIGIBILITY FOR REIMBURSEMENT:
REGULATIONS LIMITING COVERAGE FOR LABORATORY TESTS**

113. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”), codified at 42 C.F.R. Part 493. CLIA’s laboratory regulations apply to all “laboratories seeking payment under the Medicare and Medicaid [P]rograms,” and the “requirements are

the same for Medicare approval as for CLIA certification.” 42 C.F.R. § 493.

114. Medicare and Medicaid regulations both make clear that laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury, that laboratory test orders that are not individualized to patient need (or for which the need is not documented in the patient chart) are not covered services, and that claims for such services must be denied.

115. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by a laboratory. 42 C.F.R. § 410.32(d)(v). “Clinical laboratory services means the...examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.” 42 CFR § 411.351.

116. The touchstone for Medicare and Medicaid insurance coverage is medical necessity. Medicare Part B only covers services, including diagnostic laboratory services, that are reasonable and necessary for the diagnosis or treatment of an illness...” *See* 42 U.S.C. § 1395y(a)(1)(A) (“[N]o payment may be made under [Medicare] part A or part B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]”).

117. Accordingly, providers, including Quest, may only submit claims for Government reimbursement for “reasonable and necessary” medical services. In submitting claims, providers make express certifications, including a certification that the services were “provided economically and only when, and to the extent, medically necessary.” 42 U.S.C. § 1320c-5(a)(1); *see also* 42 U.S.C. § 1395n(a)(2)(B) (to receive payment for claims providers must certify that services were “medically required”).

118. Moreover, in submitting the claim form CMS-1500 to obtain reimbursement from Medicare or other Government payors for lab services, laboratories including Quest expressly certify **“that the services shown on [the] form were medically indicated and necessary for the health of the patient.”** Thus, each time a claim for payment is submitted to a Government payor, the provider expressly certifies that the services performed were medically justified. In addition, each time a provider submits a claim, the provider impliedly certifies that the service was provided in accordance with Federal and State statutes, regulations, and program rules.

119. The Secretary of HHS (“Secretary”) is responsible for specifying services covered under the “reasonable and necessary” standard and has wide discretion in selecting the means for doing so. *See* 42 U.S.C. § 1395ff(a). Typically, the Secretary acts through formal regulations and sub-regulatory

guidance.

120. Presently, the Secretary provides guidance to eligible providers pursuant to a series of Manuals, published by CMS, which are available to the public on the Internet. *See generally*, CMS Internet-Only Manuals, available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs> (last visited January 19, 2021) [hereinafter “CMS Manuals”]. The CMS Manuals offer a definitive explanation of the Medicare regulatory regime and what providers must do to comply with it. *See* 42 U.S.C. § 1395ff(a) (giving the Secretary authority to promulgate these guidelines).

121. Pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests “must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.”

122. The Medicare Benefit Policy Manual’s “Requirements for Ordering and Following Orders for Diagnostic Tests” define an “order” as “a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary...[T]he physician must clearly document, in the medical record his or her intent that the test be performed.” Medicare Benefit

Policy Manual, Chapter 15, Section 80.6.1.

123. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. 42 C.F.R. § 410.32(a). Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. § 410.32(a), so excess tests that are not used by the treating physician are not medically necessary or eligible for reimbursement.

Medicare Benefit Policy Manual, Chapter 15, Section 80.1.

124. To assess whether services are reasonable and necessary and whether reimbursement is appropriate, Medicare requires documentation of the services rendered to beneficiaries. In particular, the Medicare statute provides that:

No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

42 U.S. Code § 1395l(e); *see also* 42 U.S.C. § 1395u(c)(2)(B)(i) (“The term ‘clean claim’ means a claim that has no defect or impropriety (including any lack of any required substantiating documentation)...”).

125. Specifically, 42 C.F.R. § 410.32(d)(2) provides that labs and other entities seeking reimbursement for laboratory and other diagnostic tests are required to keep records that accurately document the medical necessity of such tests. If the laboratory does not receive documentation sufficient to justify the

medical necessity of a test from the prescribing physician, the laboratory or other entity “may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary.” *Id.* 42 C.F.R. § 410.32(d)(3) further provides:

Upon request by CMS, the entity submitting the claim must provide the following information:

- Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).
- Documentation showing accurate processing of the order and submission of the claim.
- Diagnostic or other medical information supplied to the laboratory by the ordering physician or nonphysician practitioner, including any ICD–9–CM code or narrative description supplied.

126. Medicare regulations expressly state that a laboratory’s claim for a service will be denied if there is not sufficient documentation in the patient’s medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3).

127. “As a basis for Medicare payment . . . [t]he provider . . . must furnish to the intermediary or carrier *sufficient information* to determine whether payment is due...” 42 C.F.R. § 424.5(a)(6) (emphasis added).

128. CLIA requires a laboratory to have “a written or electronic request for patient testing from an authorized person.” 42 C.F.R. § 493.1241.

129. Labs requesting reimbursement from Medicare have the burden of fulfilling Medicare's documentation requirements, and services that do not provide the requisite documentation are not payable. The burden is on the lab requesting Medicare reimbursement to provide proof documenting that a test was specifically ordered by the physician and that such order was received prior to the claim being submitted to Medicare.

130. HHS-OIG has published *Compliance Program Guidance for Clinical Laboratories* in the Federal Register. 63 Fed Reg. 45076 (Aug. 24, 1998), available at <https://oig.hhs.gov/authorities/docs/cpglab.pdf> (visited January 19, 2021).

Among other things, the HHS-OIG Guidance clarifies that standing orders are discouraged and that Medicare does not pay for tests not meeting Medicare's coverage requirements:

Therefore, Medicare may deny payment for a test that the physician believes is appropriate, but which does not meet the Medicare coverage criteria . . . or where documentation in the entire patient record, including that maintained in the physician's records, does not support that the tests were reasonable and necessary for a given patient.

* * *

a. Requisition design: While [CMS] does not design or approve requisition forms, laboratories should construct the requisition form to capture the correct program information as required by Federal or private health care programs and to promote the **conscious ordering** of tests by physicians or authorized individuals. The laboratory should construct the requisition form to **ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill.**

* * *

4. Reliance on Standing Orders

Although standing orders are not prohibited in connection with an extended course of treatment, too often they have led to abusive practices. Standing orders in and of themselves are not usually acceptable documentation that tests are reasonable and necessary...Medicare contractors can and may require additional documentation to support the medical necessity of the test. **As a result of the potential problems standing orders may cause, the use of standing orders is discouraged.**

Id. at 45079, 45081 (emphasis added).

131. Although the Guidance recognizes that physicians, not laboratories, are supposed to initiate lab orders, the OIG expects and specifically advised clinical laboratories to take affirmative steps to ensure only reasonable and necessary tests are submitted:

- Laboratories should take all reasonable steps to ensure that it (sic) is not submitting claims for services that are not covered, reasonable and necessary. *Id.* at 45079.
- The laboratory should construct the requisition form to ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill...The form should contain a statement indicating that Medicare generally does not cover routine screening tests. *Id.* (emphasis supplied).

Moreover, OIG advised that:

- If the laboratory discovers that it has in some way contributed to the ordering of unnecessary tests, the OIG believes the laboratory has a duty to modify its practices, as well as notify the physician(s) or other authorized individual(s) of its concerns and recommend

corrective action. *Id.* at 45080.

- If a test's utilization grows more than 10 percent, the laboratory should undertake a reasonable inquiry to ascertain the cause of such growth. *Id.*

Thus, the Guidance makes clear that laboratories such as Quest are expected to carefully design their requisition forms to ensure that only medically necessary tests are billed and to monitor utilization and take affirmative action to halt overutilization.

132. Significantly and directly on point, the Guidance expressly and separately addresses laboratories that provide clients with customized profiles, which are a default set of lab tests to be run each time the physician submits a specimen unless the physician expressly orders a departure from the profile. The Guidance states that the laboratories should “inform physicians that using a customized profile may result in the ordering of tests which are not covered, reasonable or necessary and that tests will not be billed,” and that the OIG takes the position that any person who “knowingly causes a false claim to be submitted to the Government may be subject to sanctions and penalties under civil, criminal and administrative law.” *Id.* at 45079-80. The danger that standing orders pose is so acute that the OIG recommended that laboratories should “have the physician sign an acknowledgement stating he or she understands the potential implications of ordering customized profiles.” *Id.* at 45079-80.

133. Quest was and is aware of this Guidance and acknowledged and relied upon it in creating the process of implementing custom panels on paper through a centralized corporate paper panel creation process, but Quest knowingly chose not to implement the same type of safeguards against false claims when implementing and encouraging the use of the lucrative Care360 ease of order panels.

THE FALSE CLAIMS ACT

134. The False Claims Act provides for the award of treble damages and civil penalties for, *inter alia*, knowingly making or using a false statement or record material to a false or fraudulent claim for payment to the United States Government. 31 U.S.C. § 3729(a)(1).

135. The False Claims Act provides, in pertinent part, that a person who:

(a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .

(a)(1)(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains...

31 U.S.C. § 3729.²

136. For purposes of the False Claims Act,

(1) the terms “knowing” and “knowingly”—

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b)(1).

THE GEORGIA MEDICAL ASSISTANCE ACT

² The False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (“FERA”), enacted May 20, 2009. Given the nature of the claims at issue, Sections 3279(a)(1) and 3279(a)(7) of the prior statute, and Section 3729(a)(1)(A) and 3729(a)(1)(G) of the revised statute are all applicable here. Prior to the enactment of FERA, Sections 3729(a)(1) and 3729(a)(7) stated that any person who:

(a)(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces a false or fraudulent claim for payment or approval; . . .

(a)(7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

is liable under the False Claims Act. Sections 3729(a)(1)(A) and 3729(a)(1)(G) apply to conduct after FERA was enacted. Section 3729(a)(1)(B) is applicable to all claims in this case by virtue of Section 4(f) of FERA, which makes the changes to that provision applicable to all claims for payment pending on or after June 7, 2008.

AND THE GEORGIA FALSE MEDICAID CLAIMS ACT

137. Prior to 2007, the Georgia Medical Assistance Act, O.C.G.A. § 49-4-146.1(b), protected the coffers of the State of Georgia from providers committing fraudulent acts against the Georgia Medicaid program. According to the Georgia Medical Assistance Act, it shall be unlawful:

(1) For any person or provider to obtain, attempt to obtain, or retain for himself, herself, or any other person any medical assistance or other benefits or payments under this article, or under a managed care program operated, funded, or reimbursed by the Georgia Medicaid program, to which the person or provider is not entitled, or in an amount greater than that to which the person or provider is entitled, when the assistance, benefit, or payment is obtained, attempted to be obtained, or retained, by:

- (A) Knowingly and willfully making a false statement or false representation;
- (B) Deliberate concealment of any material fact; or
- (C) Any fraudulent scheme or device; or

(2) For any person or provider knowingly and willfully to accept medical assistance payments to which he or she is not entitled or in an amount greater than that to which he or she is entitled or knowingly and willfully to falsify any report or document required under this article.

O.C.G.A. § 49-4-146.1(b).

138. Furthermore, “[a]ny person committing abuse shall be liable for a civil monetary penalty equal to two times the amount of any excess benefit or payment.” O.C.G.A. § 49-4-146.1(c.1)(1).

139. The Georgia Medical Assistance Act defines abuse as

a provider knowingly obtaining or attempting to obtain medical assistance or other benefits or payments under this article to which the provider knows he or she is not entitled when the assistance, benefits, or payments are greater than an amount which would be paid in accordance with those provisions of the department's policies and procedures manual which are adopted pursuant to public notice, and the assistance, benefits, or payments directly or indirectly result in unnecessary costs to the medical assistance program.

O.C.G.A. § 49-4-146.1(c.1)(2).

140. “In addition to any other penalties provided by law, each person violating [the Georgia Medical Assistance Act] shall be liable to a civil penalty equal to the greater of (1) three times the amount of any such excess benefit or payment or (2) \$1,000.00 for each excessive claim for assistance, benefit, or payment, [plus interest].” O.C.G.A. § 49-4-146.1(d).

141. In 2007, the Georgia FMCA was enacted to protect the Georgia Medicaid program from the submission of false or fraudulent claims, recognizing that such claims cause the treasury to incur serious financial losses, which result in direct harm to the taxpayers of the state and impact the provision of Medicaid services. O.C.G.A. § 49-4-168 *et seq.* The statute closely follows the wording of the federal False Claims Act. At all times relevant to this Complaint, the Georgia FMCA provided, in pertinent part, that any person who:

(1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used a false

record or statement material to a false or fraudulent claim;

(3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid; [or]

* * *

(7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit property or money to the Georgia Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit property or money to the Georgia Medicaid program,

shall be liable to the State of Georgia for a civil penalty of not less than \$5,500.00 and not more than \$11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

O.C.G.A. § 49-4-168.1.³

142. Under the statute, “knowing” and “knowingly” require no proof of specific intent to defraud and mean that a person, with respect to information:

(A) Has actual knowledge of the information;

(B) Acts in deliberate ignorance of the truth or falsity of the information; or

(C) Acts in reckless disregard of the truth or falsity of the information.

³ The Georgia Assembly amended Georgia FMCA section (a)(2) in 2012, substituting “material to a false or fraudulent claim” in place of “to get a false or fraudulent claim paid or approved by the Georgia Medicaid program.” It also amended section (a)(7) in 2012, substituting the current section for “knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay, repay, or transmit money or property to the State of Georgia.” In 2014, the General Assembly amended Georgia FMCA section (a)(3), substituting the current language for “conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.” Relator alleges there is no material difference as applied to Quest’s conduct in this case.

O.C.G.A. § 49-4-168(2).

143. The statute defines “material” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” O.C.G.A. § 49-4-168(3).

THE GOVERNMENT’S EMPHASIS ON COMBATTING LAB FRAUD

144. HHS-OIG and the Department of Justice have combatted fraudulent laboratory billing schemes similar to those employed by Quest as alleged herein, through the False Claims Act for over two decades.

145. In the wake of Operation LabScam, HHS-OIG rolled out compliance plans designed to educate labs and other healthcare providers about their obligations when billing programs like Medicare and Medicaid in order to protect those programs from fraud, abuse, and waste. The Government also promoted a “zero tolerance policy” concerning laboratory fraud.

146. On or about April 14, 2009, Quest entered into another CIA with the Government, which, among other things, required Quest to “[r]eport within 30 days of determining a matter that ‘a reasonable person’ would consider a violation of criminal, civil, or administrative laws.” But in direct violation thereof, Quest intentionally failed to report its billing for tests conducted because they were included in Care360 ease of order panels with false certifications of lab medical necessity, as defined above.

147. Between 2005 and 2010, Medicare spending on laboratory services increased 29% while enrollment in Medicare rose only 10% (a startling 19% discrepancy), which spurred HHS-OIG to conduct a study in 2014 entitled, “Questionable Billing for Medicare Part B Laboratory Services.” Not surprisingly, among the questionable practices identified most often by HHS-OIG was unusually high numbers of tests per ordering physician. As detailed below with actual examples of several ease of order panels, in 2010, Quest knew it had in place 7,500 ease of order panels across the country in Clients with IOPs. Quest billing revenue increased approximately 15% from each client that used Care360, driven by Care360 ease of order panel use.

148. In 2015, the Government prosecuted and recovered \$256 million from Millennium Health, formerly known as Millennium Laboratories, for violating the False Claims Act by billing Government payors from January 2008 through May 2015 for medically unnecessary lab services by creating custom laboratory panels that were performed with defined frequency and not in reaction to a patient’s clinical need.

149. In 2017, the Government prosecuted and recovered \$2 million from Family Medicine Centers of South Carolina, LLC for violating the False Claims Act by billing Government payors from October 2006 through February 2016 for medically unnecessary lab services by creating custom laboratory panels that were

performed with defined frequency and not in reaction to a patient's clinical need.

150. In 2018, the Government prosecuted and recovered \$1.7 million from Brattleboro Memorial Hospital for violating the False Claims Act by billing Government payors from January 2012 through September 2014 for lab tests that lacked the necessary documentation to support reimbursement.

151. In 2020, the Government prosecuted and recovered \$43 million from Genova Diagnostics, Inc. for violating the False Claims Act by billing Government payors from July 2015 through June 2017 for medically unnecessary lab services by creating custom laboratory panels that were performed with defined frequency and not in reaction to a patient's clinical need.

QUEST'S FRAUDULENT CONDUCT AND FALSE CLAIMS

The Post-LabScam Centralized Custom Panel Process and its Compliance Guardrails

152. In response to the Government enforcement in Operation LabScam, the CIAs to which Quest was subjected, and the Government's explicit 1998 Guidance for Clinical Labs regarding how to legally create and use test requisition forms for panels of tests, in approximately 2000, Quest created and implemented a centralized corporate process for the corporate-monitored creation and use of custom panels of tests that could be selected on paper order forms.

153. Quest issued policies around the creation and use of paper-ordered custom panels. Significantly, in 2000, Quest set forth its policy on custom panels

requiring “rigorous controls:”

Only clients may select the test components contained in customized panels and profiles. To facilitate the ability of a client to order any testing he or she believes to be medically appropriate for the treatment of his or her patients, **Quest Diagnostics will allow clients to order custom panels and profiles, but only with rigorous controls emphasizing physician choice, proper disclosure and client education.**

...

Before clients may have custom panels or profiles activated, they must sign a form in which they verify, at a minimum, that they are aware of the test components, the CPT codes for the components and the Medicare reimbursement rates for the tests comprising their custom panels and profiles.

Your Compliance Policy Handbook at p. 11 “Custom Panels and Profiles Verification” (emphasis added).

154. In 2002, in a file named “Panel disclosure position paper.doc,” Quest set forth its “Quest Diagnostics Incorporated 2002 Panel/Profile Disclosure Position Statement.” That Statement includes the following:

Quest maintains an ongoing commitment to, and responsibility for, providing education to our clients concerning the ordering, performing, and billing of clinical laboratory tests. Specific to custom panels, the Model Compliance Plan issued by the Office of Inspector General (OIG) states that laboratories that continue to offer clients the opportunity to request customized panels should provide annual written notices that: (1) explain the Medicare reimbursement paid for each component of a panel; (2) inform physicians that the use of a custom panel may result in the ordering of tests that are not covered, reasonable, or necessary; and (3) inform physicians that ordering medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties.

155. In the June 2004 *Your Compliance Handbook*, the Test Ordering Policy was that, “Quest performs only those tests specifically requested by an

ordering physician or other person authorized to order laboratory testing under state law. The company must ensure that laboratory tests are clear and are received or confirmed in writing.” *Id.* at p. 107. An “unclear test order” is defined as “one that is “not an exact match with a test name or a test code: . . .” *Id.* at p. 108.

156. In a July 1, 2008, revision to the Compliance Policy on Custom Panels and Profiles Verification to include a “Compliance Operations Procedure: Custom Panels & Profiles Verification.” In that Procedure, Quest assigned responsibility for “reviewing, training, implementing and monitoring employee compliance with the Custom Panels and Profiles Verification policy, as found in Your Compliance Handbook and this procedure” to the BU Managing Director and the BU Sales Director. It states that “the Sales Representative is responsible for completing the appropriate process steps when a client requests a custom panel or profile.” The Procedure was approved by John Nosenzo, Vice President Sales and Marketing, Carl Landorno, Privacy Officer and Director, Compliance Operations. The procedure details the use of corporate custom panel request forms and the use of the appropriate PAF for each type of Client. The 2008 Policy, itself, reiterates the need for “rigorous controls” and actually cites the HHS OIG Compliance Guidance of Laboratories discussed above:

| | |
|----------------------------------|---|
| POLICY | Only clients may select the test components contained in customized panels and profiles. To facilitate the ability of a client to order any testing he or she believes to be medically appropriate for the treatment of his or her patients, Quest Diagnostics will allow clients to order custom panels and profiles, but only with rigorous controls emphasizing physician choice, proper disclosure and client education. |
| Reason for Policy | Clients sometimes request Quest Diagnostics to group two or more tests together as a custom panel or profile for ordering convenience. By offering customized panels and profiles, Quest Diagnostics facilitates each client's ability to order testing that the client believes to be medically appropriate for the treatment of the client's patients. |
| When to Use Policy | Use this policy whenever a client requests two or more tests be grouped together as a panel/profile for the client's ordering convenience. |
| Supporting Documents | <i>HHS OIG Compliance Program Guidance for Clinical Laboratories</i> |
| Key Points for the Client | <ul style="list-style-type: none"> • Payers, including Medicare, are concerned about unnecessary testing and consider ordering combinations of tests (panels/profiles), rather than ordering tests individually, a possible source of unnecessary testing. • Quest Diagnostics will always offer each component of a panel/profile individually. • Quest Diagnostics implements a verification process that discloses the test components, CPT codes and reimbursement implications of each component of the panels and profiles, to the client. • The verification process also helps to ensure that the client has the convenience of ordering custom panels and profiles while Quest Diagnostics continues to facilitate the client's ability to order only tests that are medically appropriate to treat the client's patients. |
| Form(s) | <ul style="list-style-type: none"> - QLS Sites - Centralized Requisitions (<i>See reverse side for a listing of requisitions.</i>) - Non-QLS Sites - Decentralized GTR and Medicare/Medicaid Requisitions (<i>See reverse side for a listing of requisitions.</i>) |

Custom Panels and Profiles Verification

157. These paper-selected custom panels had to be requested in writing to corporate using a Quest corporate “custom panel request form,” and were not available for selection by a Client until corporate received the appropriate Physician Authorization Form that included warnings to the provider about the risk of over ordering of tests in a panel and an agreement by the provider that he or she would notify Quest if he or she determined that selection of the panel had resulted in ordering a test that was not medically necessary.

158. For the centralized paper panel creation process, Quest created and used three different Physician Authorization Forms (“PAFs”), depending on the nature of the Client: one for a single provider office, one for a multi-provider

practice, and one for long term care facilities, hospitals and home healthcare agencies. Each included the following warning to the providers of the illegality of ordering a test that is not clinically medically necessary:

When you order testing for any Medicare or Medicaid patient, you should only order those tests that are medically necessary for the diagnosis and treatment of the patient.

Using a custom panel may result in the ordering certain tests that are *not* medically necessary for the patient. Accordingly, where not all of the tests in the custom panel are medically necessary for the diagnosis and treatment of the patient, Quest Diagnostics provides you with the option of ordering any of the tests in the custom panel individually or ordering a less inclusive panel. **The Department of Health and Human Services takes the position that a physician who orders medically unnecessary tests for any Medicare or Medicaid patient may be subject to civil penalties.**

Quest Diagnostics Incorporated Physician Authorization Form for Custom Panels, Physician Practice Group Form (2003) (bolding emphasis added).

159. Each PAF included a specific acknowledgement by the physician signatory that:

Prior to ordering any Custom Panels, each ordering physician must have reviewed this Physician Authorization Form for Custom Panels, including information listed above as to the [contents of] the Custom Panels and the Notes. With respect to the Custom Panels, each ordering physician must understand the following:

1. The components of the Custom Panels listed above;
2. The Medicare reimbursement for the tests included in each panel;
3. These Custom Panels will appear as separate check-off items on this facility's or agency's requisition;
4. By selecting the test order code for a Custom Panel, the ordering physician is electing that all components included in the panel be performed;

5. The components of a Custom Panel may be charged separately to Medicare, Medicaid and other third party payors using the CPT codes indicated; and
6. That then ordering physician always has the option to order separately one or more of the individual components of each panel.

©2003 Quest Diagnostics Inc. Physician Authorization Form for Custom Panels;
Long Term Care Facility, Hospital and Home Health Agency Form.

160. In addition to limiting the creation of custom panels to those created by corporate in the centralized process, Quest automatically sent every client that ordered a custom panel created in that process an annual notification letter that included the panel components, CPT Codes and Medicare National Limitation Amount reimbursement for each test.

161. But in developing Care360 and moving its Clients to electronic ordering of tests, Quest decided to ignore the Government enforcement in Operation LabScam, the corporate integrity agreements into which Quest had entered, the directly on point Guidance for Clinical Labs regarding how to legally create and use test requisition forms for panels of tests, and to bypass its own centralized custom panel process. Quest Care360 functionality included the ability for Quest sales reps and phlebotomists to create custom panels directly in a Client's office without any of the corporate panel creation process safeguards; it was the same product, custom panels, but Quest decided to maximize its revenue by doing away with all of the compliance measures it had set up around the use of that

product.

QUEST'S DEVELOPMENT OF ELECTRONIC CUSTOM PANELS

162. In 2001, after the LabScam prosecution, publication of the HHS OIG Guidance for Clinical Laboratories, the Smithkline Beecham CIA to which Quest became subject and during Quest's implementation of its centralized, corporate paper-selected custom panel process, Quest acquired MedPlus, Inc., a healthcare information technology company. As discussed above, working with its new subsidiary, Quest developed a computerized software platform to interface with Client medical offices' electronic medical records and allow electronic, in-office ordering of Quest tests.

163. In 2002, Quest advanced customer connectivity capabilities by deploying the TOROL (Test Orders and Results On-Line) product, which Quest's sales force marketed to providers nationwide for its ease of online test ordering. Quest designed TOROL with the capability for its employees to build custom panels. Quest's President and Chief Operating Officer Surya Mohapatra indicated the TOROL product increased Quest's "stickiness" with customers and immediately increased online ordering by 20%.

164. In January 2002, Quest's electronic TOROL orders totaled approximately 25,000 with approximately 2,000 registered clients. By September 2002, the total orders grew nearly 1,000 percent to 229,000 with more than 14,500

registered clients.

165. In 2003, Quest launched eMaxx Internet portal to providers nationwide with a goal of more than 11,000 customer placements in 2003. The eMaxx web portal enabled providers to order diagnostic tests and review laboratory test results online, as well as view and share patients' clinical information from many sources. eMaxx, which was also designed with the capability for employees to build custom panels, became the gateway for physicians to access Quest's nationwide TOROL service. Quest described eMaxx as a "hook" for getting more lab business, with one Western North Carolina sales manager noting that within 60 days, Quest added \$65,000.00 per month in business using eMaxx as a lead-in product.

166. In 2004, TOROL and eMaxx became known as Care360.

167. Quest internally maintained an ongoing list of problems and projects regarding its electronic ordering systems—TOROL, eMaxx, Care360—utilized across the country, including California, New York, Washington, Florida, Texas, Louisiana, and Maryland, and as far back as June 29, 2002. In her role as a compliance officer, Relator was privy to and reviewed this document, which referenced nationwide providers utilizing thousands of electronic ease of order panels.

168. When Quest purchased other labs, it migrated their electronic systems

(e.g., METLAB, SCAN, Cclink, LabConnect, PC Connect, Results On-Line, Entrée 1, Entrée 2, Merit, Docnet, Clinscan, Unilab Direct, 4Medica, LabLink) into its Care360 platform, re-entering the acquired labs' custom panels without obtaining physician authorizations for the tests within each custom panel.

169. Quest designed Care360 to enable not just electronic ordering of individual tests, but the selection of custom panels of tests using only the name of the panel checked on a scrip pad or other order form to generate in Care360 an electronic test requisition that ordered and then automatically billed each test in a panel. At the time, as later admitted to Relator by Quest's Compliance Officer for Sales and Marketing, J.H., Quest was well aware of the enormous compliance risk of illegally billing for tests that are not Reasonable and Necessary/medically necessary as was required, when it launched Care360, but took no steps to curb that abuse.

170. After developing the software to allow ease of order panels directly in Care360, Quest launched an aggressive campaign promoting Care 360 and encouraging its Clients to utilize ease of order panels in Care360. The campaign was successful: In 2005, 45% of Quest's lab orders were transmitted electronically through Care360; by 2008, the volume had grown to fully 70% of all orders being electronic through Care360.

171. As remuneration to physician practices that ordered a high volume of

tests (high referring Clients), Quest set up Care360 in their offices and provided a full-time, in-office phlebotomist to perform blood draws and initiate test requisitions in Care360. Revenue generated by the provider to Quest determined if the provider was “worthy” of having a Quest phlebotomist. In order to be eligible to obtain a Quest phlebotomist, Clients had to be profitable enough to Quest, with the assumption that the Clients would refer to Quest all of their Medicare and Medicaid testing services.

172. As a further inducement to high-referring physician practices, Quest offered to perform lab tests billable to insurers by the Clients, at heavily discounted, even below cost, pricing for privately insured patients and allow the physician to bill the patients’ private insurers for the full price of the test in order to make a profit. In exchange, the physicians were required to refer to Quest all of their Medicare and Medicaid patient testing services.

173. In sharp contrast to the centralized paper custom panel process, when implementing Care360 in Client offices Quest personnel; sales representatives and phlebotomists created ease of order panels in the software (which panels did not expire) and could be selected for use by any provider, regardless of who created the panel initially. Critically, none of the providers creating or using Care360 ease of order panels were required to sign a PAF or otherwise indicate that he or she even knew what was in the Care360 panels.

174. Quest took no steps to determine whether every Provider selecting a Care360 ease of order panel knew what tests were in the panel when he or she selected it.

175. When an ease of order panel was selected by a provider in Care360, an electronic test requisition form was generated in Care360 and a bar code printed in the Client office for application to the patient's physical specimen, whether blood, urine or tissue. Inside Care360, the ease of order panel was "unbundled" and each individual test in the panel was performed and billed separately to the Government. When a provider selected an ease of order panel, he or she was not selecting patient-specific tests determined by the treating physician on the date of the office visit to be medically necessary based on an individualized assessment of a specific medical condition.

176. The Care360 ease of order panels do not expire. Multiple providers in a Client office can and do utilize the same Care360 ease of order panels, regardless of when or for which provider Quest created the panels. Quest does not obtain or maintain an acknowledgment or authorization from each provider within the office to demonstrate his or her knowledge of, or intent to order, the individual tests within the Care360 ease of order panels created by Quest without expiration.

177. When treating a Government beneficiary, a provider has little or no time or incentive to undertake Quest's intentionally laborious process of

identifying each test in an ease of order panel and will simply select an ease of order panel if he or she understands that the desired test(s) are at least within the panel. The provider's priority and concern is providing treatment to the Government beneficiary, and the fact that other tests will be performed and billed to the Government is not part of the provider's panel selection process or even something that occurs to him or her in a busy day of treating patients. Hence, the need for the Government's imposition on the lab as the biller to truthfully certify that each test is medically necessary and thus eligible for reimbursement, i.e., that the test was ordered by the treating physician, for a specific patient, on a specific date, to address a specific medical condition.

178. Quest knew its Care360 ease of order panel process was resulting in Quest submitting false claims, and, in 2007, created procedures that were designed to verify that each provider utilizing an ease of order panel actually knew of and intended to order each individual test included in the panel for his or her patient for a specific medical condition on the date the panel was selected. Quest called this draft set of policies and forms "Alternative Care360." Quest never implemented Alternative Care360 because the unbridled use of Care360 ease of order panels was so lucrative.

179. The following screen shots show how sales reps and phlebotomists built ease of order panels in Care360:

Electronic Requisition System - Microsoft Internet Explorer provided by Quest Diagnostics

File Edit View Favorites Tools Help

Back Forward Stop Search Favorites Media Print

Address http://qdcws0204clis:443/scripts/mgwms32.dll Go Links »

Care360
A MedPlus Solution

[Help] ?

Custom Profile Definition

New Custom Profile

Client Number: TEST CLIENT (HQ) (97502840) ▼

Profile Code: Profile Description: Action

Existing Custom Profiles

| Profile Code | Profile Description | Action |
|--------------------------------------|-------------------------|----------|
| <input type="radio"/> TESTPROF | testing | [delete] |
| <input type="radio"/> RUTH'SNEW | Testing9.5 | [delete] |
| <input type="radio"/> 5555 | this is a test | [delete] |
| <input type="radio"/> ABZ | Chemistry Profile | [delete] |
| <input checked="" type="radio"/> LAM | LAM East or Order Panel | [delete] |

Components for:

Add Order Code: max: 35 allowed Show Quick List ☒

| | | |
|------|-------------------------|----------|
| 6399 | CBC (INCLUDES DIFF/PLT) | [remove] |
| 7020 | THYROID PANEL | [remove] |

Quest Diagnostics

180. To avoid any unwanted scrutiny, Quest trained its phlebotomists and sales representatives to create ease of order panels in Care360 outside the presence of the physician. To further hide the contents in the automated panels, Quest designed and created Care360 for it to be laborious and difficult for non-Quest personnel to determine the individual test components in each ease of order panel. The following is a page from Quest's Care360 Customer Instruction Guide that was stored on the Quest Intranet that further demonstrates Quest's intention to conceal the panel creation process from physicians or their practice's office managers, instead relegating this function to administrative staff and lab techs:

Lab Ordering Prioritization Chart

The illustration below represents the 4 points of contact in most physician's office. This chart will help you identify application focus areas for your office training based on who is participating in the training. **KNOW YOUR AUDIENCE!**

| | Physician | Office Manager | Administrative Office Staff | Lab Tech |
|--|-----------|----------------|-----------------------------|----------|
| Navigating the Lab Orders and Results | ✓ | ✓ | ✓ | ✓ |
| Setting up Custom Profiles (Insurance, Order, & Diagnosis Grids) | | | ✓ | ✓ |
| Placing Orders | | | ✓ | ✓ |
| Viewing Results | ✓ | ✓ | ✓ | |

181. Quest personnel designed and created these panels and profiles by determining which laboratory tests were most profitable for Quest to perform and were most commonly ordered by physicians. Quest utilized financial incentives to encourage its sales representatives to promote ease of order panels, as well as certain profitable tests within the panels and profiles, to its client providers.

182. Quest's sales representatives were taught to create ease of order panels in Care360 when the software was initially rolled out and were trained on creating them at Quest's mandatory training sessions for all new sales representatives, known as the Corporate Sales Training Academy. On October 13, 2010, a full year after Relator began raising concerns to Quest management regarding Quest's submission of false claims when billing for tests in Care360 ease

of order panels, two newly hired sales representatives, T.F. and J.S., personally informed Relator that they were taught to build ease of order panels in Care360 for Quest's clients while at the Corporate Sales Training Academy.

183. Physicians were routinely encouraged by Quest personnel to order the then new, more profitable ease of order panels, as opposed to ordering only individual tests. Relator saw in the Care360 Project Pipeline in the Quest intranet the creation and use of Care360 ease of order panels in 2004 across the United States. Based on discussions concerning improvements being sought internally in the Care360 software, Relator learned the ease of order panels were everywhere: Without even searching for them, she saw such panels in Quest business units in Washington, Oregon, California and Ohio. In just her own business unit (the SE BU), she saw ease of order panels dating back to 2004.

184. Physicians were falsely led to believe that tests included in the ease of order panels created by Quest were performed at no or low cost as part of a bundled rate, similar to CMS-approved AMA panels, such that the cost of the panels were lower than the combined costs of the individual tests. In fact, when providers received patients' test results, certain tests were broken out in detail, which made Quest's billing of every test in the automated panels difficult to decipher.

185. Unknown to the physicians, the ease of order panels were not billed to

Government payors as a discounted panel or as part of a bundled rate. Instead, the tests in the panels were “unbundled” by Quest, and each test was billed to Government payors as an individual test. As a result, Quest billed Government payors for services that Quest did not know were medically necessary and lied about its lack of knowledge to obtain payment of each claim.

186. Custom panels built electronically in Care360 bypassed all of Quest’s procedures and policies regarding physician disclosure. Physicians had no way of knowing how the custom panels would be billed. Many test results display the individual analyte levels that make up each test, which made it especially confusing to physicians to decipher which of the results comprised tests that were billed. For example, the test “Protein, Total and Protein Electrophoresis” displays in the lab result with values for the individual analytes listed—Albumin, Alpha-1-Globulins, Alpha-2-Globulins, Beta Globulins, and Gamma Globulins:

| Test Name | In Range | Out Of Range | Reference Range | Lab |
|--|----------|--------------|-----------------|-----|
| PROTEIN, TOTAL AND PROTEIN ELECTROPHORESIS | | | | |
| PROTEIN, TOTAL | 7.1 | | 6.2-8.3 g/dL | AT |
| PROTEIN ELECTROPHORESIS | | | | AT |
| ALBUMIN | 4.0 | | 3.5-4.7 g/dL | |
| ALPHA-1-GLOBULINS | 0.2 | | 0.1-0.3 g/dL | |
| ALPHA-2-GLOBULINS | 0.9 | | 0.5-1.0 g/dL | |
| BETA GLOBULINS | 1.1 | | 0.8-1.4 g/dL | |
| GAMMA GLOBULINS | 0.9 | | 0.6-1.6 g/dL | |
| INTERPRETATION | | | | |

187. As a result, physicians are unable to determine based on reviewing the lab results what tests Quest billed to the Government.

188. Quest’s sales representatives often discussed that Quest’s revenue from a Client and the Client’s average number of tests per requisition increased by

15-20% when the client used Quest's ease of order panels in Care360.

189. Quest's ephemeral Alternative Care360 was designed to meet Quest's burden of truthful certification by documenting for Quest the physician's knowledge of and intent to order each of the tests in an ease of order panel. Alternative Care360 likely was insufficient to satisfy Quest's obligation to truthfully certify the medical necessity of any test for which it billed the Government, but it adds to the proof that Quest knew its Care360 ease of order panel procedures were not sufficient to meet its obligation. In Alternative Care360, Quest created documentation that required physicians to execute an acknowledgement of, and authorization to perform and bill for, tests included in each ease of order panel.

190. Set forth below are examples of some Alternative Care360 documentation (deliberately not implemented) that show Quest's knowledge of the need to take significant steps to be able to truthfully certify to the Government that tests in Care 360 panels were Reasonable and Necessary.

191. Alternative Care360 Customer Defined Panel Setup Process and Acknowledgement:

Use only with Care360™.

This process and acknowledgement cannot be used for test offering on paper requisitions.

Account Number:

1. Review bullet points below with the physician.
2. Obtain the customer defined panel name, the component test order codes and test names from the physician.
3. Define the customer defined panel(s) per instructions in this document.
4. Define the customer defined panel(s) on test order grid if requested by the physician.
5. Have the physician review the prepared customer defined panel and test order grid if indicated.
6. Define for the customer the options for making changes or corrections to the customer defined panel(s).
7. Have the physician sign and date this acknowledgement.
8. Provide the physician with a copy and place a copy in the client file.

I am authorized to act on behalf of all the physicians or medical staff and acknowledge that:

- I always have the option to separately order one or more of the individual components of any customer defined panel.
- Customer defined panels include tests that are grouped together for my ordering convenience in Care360™, however the lab will receive orders as individually ordered tests and will bill them as individual tests.
- I will notify Quest Diagnostics immediately if I determine that the components of the customer defined panel are not consistent with the testing that I intended to order, and,
- I, or my staff, have the ability to make corrections or changes to the customer defined panel(s) at any time.
- I have granted authorization to a Quest Diagnostics representative to enter the requested information under my Care360™ login, supervised the entry, and did or will not provide the representative with my user ID and password.

| | | | |
|-------------------------------------|-----------------------|-------------------------------------|-----------------------|
| Customer Defined Panel Name: | | Customer Defined Panel Name: | |
| Component Test Code | Component Name | Component Test Code | Component Name |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| Customer Defined Panel Name: | | Customer Defined Panel Name: | |
| Component Test Code | Component Name | Component Test Code | Component Name |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

I have reviewed the customer defined panel(s) above built per my request, and agree they are defined as I intended.

Printed name

Date _____

Printed Name

Date _____

193. In Alternative Care360, Quest even created Q&A for training phlebotomists that they could NOT create ease of order panels and that a physician had to sign a PAF for the ease of order grid to be created:

**QUEST DIAGNOSTICS
PHLEBOTOMY SERVICES COMPLIANCE: QUESTIONS AND ANSWERS**

| | | |
|----|---|--|
| 19 | If a client always has his patients use the Care360 system to order panels to check client every wants? | <p>“The convenience of ordering custom panels must not compromise the physician’s obligation to determine which tests . . . are medically necessary [P]hysicians who order ‘medically unnecessary’ testing for Medicare or Medicaid patients may be subject to civil penalties. The indiscriminate use of custom panels without regard to the uniqueness of each patient may result in Medicare [and/or] Medicaid . . . reimbursing for non-covered services. Accordingly, . . . it is in the best interest of physicians . . . and Quest Diagnostics that custom panels are offered only with rigorous controls that emphasize physician choice, proper disclosure and client education.”</p> |
|----|---|--|



I

**Alternative Care360™ Lab Test Order Grid Setup Process and Acknowledgement
Alternative Care360™ Customer Defined panel Setup Process and Acknowledgement
Frequently Asked Questions (FAQs)
8/22/2007**

- Q3. Can the nurse or office manager sign the acknowledgement instead of the physician?**
- A. No. The physician must sign the acknowledgement. Although we recognize that most often it is the office staff that is using the Care360™ rather than the physician, we must still take measures to help ensure that we are entering the tests the physician requests. Therefore, although the authorized staff may play a large roll in completing this paperwork and using the system, the physician has ultimate approval and responsibility for the testing that is ordered using these tools.
- Q4. Can the physician email their acknowledgement rather than signing the acknowledgment form?**
- A. No. At this time, we must get the physician’s actual signature on the acknowledgment form. Since the Quest Diagnostics employee must be in the client’s office to set up the grids and/or panels, this should not be an additional burden.

194. In October 2010, after Relator had been fighting to stop the unbridled

fraudulent use of Care360 ease of order panels for more than a year, she was finally informed of the existence of the Alternative Care360 procedures for the first time: In October 2010, Quest's Vice President of Compliance and Chief Compliance Officer, Tim Sharpe, told Relator that the Alternative Care360 procedures had been developed in 2007, but the business unit did not want to implement it.

195. Also in October 2010, Relator was informed by another Quest compliance officer, in Ohio, that she had also reported Quest's noncompliant use of Care360's ease of order panels to VP Sharpe on multiple occasions, but she never received a response.

196. Despite knowing the rules governing payment by Government payors for laboratory tests and creating processes and documentation to effectuate those rules, in Care360, Quest deliberately, intentionally, and recklessly failed to obtain signed acknowledgement forms from physicians authorizing or indicating their intent to order each test in an ease of order panel or custom profile that was billed to the Government or to otherwise meet its obligation to truthfully certify that tests it billed to the Government were medically necessary. But Quest did not know and indeed made it impossible for it to know if tests included in Care360 ease of order panels were known to and intended by each provider selecting a panel.

**RELATOR'S CRUSADE TO STOP QUEST FROM SUBMITTING FALSE
CLAIMS AND REPRESENTATIVE EXAMPLES OF FALSE CLAIMS
SUBMITTED BY QUEST**

197. In the spring of 2009, as a conscientious Compliance Officer who believed that Quest as a corporation intended to comply with all of its legal billing obligations, Relator learned that failures to adhere to the Quest Test Order Policy and the corresponding Test Order Procedure was one of the top policy violations cited by Quest Internal Audit across the country, and that such failures were also one of the top reasons Quest Compliance Officers issued formal Incident Reports to conduct Compliance investigations. She assumed that this high volume of noncompliance was due to individual weaknesses in effectuating Quest-authorized practices. So, she undertook an investigation of her business unit's adherence to the Test Ordering Policy. The Quest Test Order Policy is attached hereto as Exhibit A.

198. Relator selected the Clients in her BU that had in office phlebotomists ("IOPs") because those were the Clients that ordered the most Quest tests, and she commenced comparing the providers' original orders for tests (scrip pads or other hard-copy order forms) for Medicare or Medicaid patients and compared those orders to the tests ordered in Care360/the test requisitions in Care360.

199. These materials were all available to Relator because the Client IOP sent the Provider's original paper order along with the printed Care360 requisition

to the laboratory with the specimens. The lab scanned all of the documents into an imaging system that the Relator could view. The Care360 electronic test requisition shows each test that was conducted on the patients' specimen(s).

200. She discovered that there was often poor correlation between the individual tests in the provider's order and the Care360 test requisition. She discovered that IOPs were creating "living," hand-written translations between tests ordered in a Client office and the tests by a different name offered by Quest. These hand-written translations were modified over time in Client offices in a haphazard fashion resulting in a chaotic guess often being made as to what test the Client intended to order and were referred to as "cheat sheets."

201. On June 23, 2009, Relator received an email from a Patient Services Manager overseeing IOPs in Quest's Nashville BU asking if IOPs could utilize Care360 groupings of tests in Care360 to order tests for Clients. Relator did not yet know about the Care360 ease of order panel functionality and simply responded that all tests conducted had to exactly match the provider's original order.

202. She continued getting similar questions from Patient Services Managers in her BU, so she set up a re-training session for them to take place in Atlanta on July 30, 2009. Relator selected a 2016 Compliance Power Point presentation on the centralized corporate custom panel process to use in the

presentation. She presented those slides on July 30, 2009, and the Patient Services Managers responded by telling her that Sales Reps and IOPs were building custom panels, themselves, directly in Care360 and that they (the Managers) thought the enabling of this localized process had replaced the centralized corporate custom panel creation process. At the session, neither Relator nor the attendees could figure out how Sales setting up custom panels directly in Client office could be compliant. At the end of the training session, the attendees were fearful that they did not have the power or authority to stand up to the Sales Department and said Relator had to “have their backs” for them to do anything about the Care360 panel problem.

203. Following the training session, Relator promptly notified M.H., the Regional Compliance Officer over the SE BU and Lynn Wiser, Quest’s Director of Compliance Audit, Product Offerings and Refunds, of the Care360 panel issue – that Quest was doing tests ordered in Care360 not reflected in the provider’s order or in a panel created via the centralized corporate custom panel request process on which there were many Quest policies and procedures, and awaited their telling her how to fix it.

204. Relator started receiving “cheat sheets” being used in various Client offices in her BU. She saw that some of the cheat sheets included panels of tests in Care360 and she asked who created the panels. She reviewed actual examples of

what Quest billed for Medicare or Medicaid patients when the order process started with the selection of a Care 360 ease of order panel.

205. Relator kept M.H. and Ms. Wiser informed of her findings regarding Sales employees bypassing the centralized paper custom panel creation process and building custom panels directly in Care360 instead. They responded to her that they had reported it to Quests' corporate Compliance leaders, including Carl Landorno and Tim Sharpe, and that Landorno had responded that he wanted Relator to put together examples that could be shown to senior Compliance leaders in the upcoming Compliance Management Team Meeting at corporate.

206. Although Relator was told by corporate Compliance leaders that it was not possible to identify who created Care 360 ease of order panels, in November 2009, Relator reached out to Medplus, directly, and employee Roy Blake provided her with a spreadsheet showing every ease of order panel in Care360 in a Client office with an IOP in the SE BU that included who created the panel. The spreadsheet identified the Quest employee who had created the panel, when it was created, and listed each of the tests included in the panel. Relator sent the spreadsheet to M.H. and Ms. Wiser.

207. Relator also asked Mr. Blake what if any steps Quest could take to make sure it knew whether each test in a Care360 ease of order panel was medically necessary each time a panel was selected. He informed Relator that it

would take him only 5 minutes to add a pop-up notification in Care360 that would tell Quest personnel creating ease of order panels to obtain signed acknowledgement forms from the physician for whom they were creating the panels, which form would identify and authorize the specific list of tests that the physician says he or she would intend to order each time he or she selected the panel. Relator passed this information on to M.H. and Lynn Wiser because she knew she did not have the authority to implement this national step in the right direction. But Quest deliberately, intentionally, and recklessly failed to implement this notification feature or any other safe guards against false claims in Care360.

208. M.H. reported to Relator in 2010 that at the time, there were 7,500 ease of order panels created in Care360 in Clients with IOPs across the United States. She did not say how many existed in Client offices without IOPs.

209. Ms. Senters knew what a high-risk issue it was, so she each day while she ate lunch at her desk, she reviewed original orders and the corresponding Care360 test requisitions for Medicare and Medicaid patients. She saw tremendous discrepancies on many patient orders and for each account, she called the Phlebotomy Supervisor with oversight over the Client office and asked if they had a translation Letter in place signed by the provider.

210. She thought that maybe because Quest had a copy of the provider's original order and the Care360 test requisition that perhaps there was a quality

control process implemented in the laboratory where someone reviewed the doctor's original order versus the Care360 requisition. In her investigation she later learned that was not the case but that Quest had designed the Care360 software to allow exactly what she was seeing.

211. Seeing that the original order for tests from the provider did not match the tests ordered in Care360 (in the test requisition) prompted Relator to see what tests got billed. She met with Quest Billing Department employee Y.P. in Atlanta to pull actual claims for Medicare and Medicaid patients and compare them to Care360 test requisitions and the original orders from the providers that had been scanned into Care360. Ms. Senters focused on pulling claims that had been submitted to Medicare or Medicaid because in the Compliance Officer role she had been trained to focus on those Government programs' billing requirements, and potential violations of the False Claims Act, the Stark Law and the Anti-Kickback Statute.

212. She saw that the tests billed to Medicare or Medicaid were the tests listed in the Care360 test orders/requisitions. Those tests were not in the original orders. Relator checked to see if custom panels had been set up via the established centralized corporate process described above for the Clients whose patients' testing she saw being billed to the Government. None of them had such custom panels. Relator did not yet know of the Care360 ease of order panels being rated

by Sales and phlebotomists in Client offices.

213. As part of her investigation into the disconnect between the original orders and the test that got done and billed to the Government, Ms. Senters came into the Atlanta lab at night when the Specimen Processing group worked because this was when all of the specimens were in the lab and she could follow the ordering-conducting-billing process all the way through from specimen entrance into the building, specimen accession, testing, and how each then got actually billed to the Government. She talked to the Specimen Processing Manager, T.M., because her team were first to touch the specimens in the lab and asked her if her team reviewed the provider's original order and compared it to the Quest requisition. She said, "no." T.M. explained that although the original order gets scanned and saved, the Care360 test requisition dictates what tests get done and billed to the Government. She said the testing instruments read the Care360 barcode on the patient's specimen and that dictates what tests get performed and billed.

214. Ms. Senters learned from Quest Billing Department personnel that the list of tests in the Care360 test requisition is automatically uploaded into the Lab Information System (known as the "LIS") and is electronically transmitted to the Billing System. Each test in the Care360 test requisition gets conducted and billed.

215. Ms. Senters knew it was a violation of at least the Quest Test Order

Policy to do and bill test that had not been specifically ordered by the treating provider. She created spreadsheets on a patient by patient basis of discrepancies between the original order and the tests done and billed and took them to continued meetings with Billing Department employees down the hall from her office in Atlanta. The Billing Manager, Y.P., set her up with a Billing Service Representative to continue reviewing examples of how the tests in Care360 ease of order panels for Medicare and Medicaid patients had been billed. She learned how to use the Quest Billing system (referred to as “QBS”) and began using it in her own office.

Representative Examples of False Claims

216. Based on her investigation, Relator herein provides representative examples of Quest’s fraudulent conduct and false claims to the United States. The following is a copy of a Quest Client’s pre-printed, hard-copy script pad (the provider’s original order) that includes two Care 360 ease of order panels, and specific information regarding Quest claims billed to the Government for the tests in those panels with false certifications by Quest that each test was Reasonable and Necessary. Relator personally reviewed the actual billing data for each of the claims to the Government depicted below. Relator has a spreadsheet of all of the Care360 ease of order panels in existence in the SE BU as of November 2009. The spreadsheet includes the panel name, creation date, identity of employee who

created it, and lists each Quest test included by the employee in the panel.

217. On May 15, 2009, Quest phlebotomy group lead C.D. (identified by initials here for privacy purposes) created an ease of order panel in Care360, referred to as the “Arthritis Panel,” for Quest Client Dr. Benjamin Abraham, a physician practicing at 3020 Centerville Highway, Snellville, Georgia 30039. Quest employee C.D. populated the “Arthritis Panel” in Care360 with the following tests:

- Rheumatoid Factor (CPT 86431);
- Basic Metabolic Panel with EGFR (CPT 80048);
- Anti-Streptolysin O (CPT 86060);
- Anachoice (TM) Screen with Refl to titer, IFA (CPT 86038);
- C-Reactive Protein (CPT 86140);
- Sed Rate by Modified Westergren (CPT 85652); and
- CBC (includes Diff/PLT) (CPT 85025).

218. Once the “Arthritis Panel” was created by Quest employee C.D., it was in place for Dr. Abraham’s practice indefinitely, and it could be selected on pre-printed, hard-copy script pads as well as on Care360’s electronic platform. A redacted copy of the pre-printed, hard-copy paper lab requisition, created by Quest for use in Dr. Abraham’s office, appears below and includes the “Arthritis Panel,” the “Anemia Profile” (another ease of order panel), and a number of individual

tests:

Name of Patient: [REDACTED] Acct #: [REDACTED]
 Date of Service: 10/22/09 DOB: [REDACTED]

☒ CMP w/Uric Acid 10231, 905 ☒ CBC 6399 ☐ T3 859 ☐ T4 867 ☒ TSH 899
☒ Free T4 866 ☐ BMP 10165 ☒ Lipid 14852 ☐ HgA1C 496 ☒ Vit D 17306
☐ PSA 5363 ☐ P/IInr 8847 ☐ RPR 36126 ☐ Rheum. Factor 4418
☐ Hepatic Panel 10256 ☐ Iron 571 ☐ HS-Crp 10124 ☐ HSV 1/2 IgG 6447
☐ Pap w/HPV 58317 ☐ Pap rfx/HPV 58316 ☐ Hepatitis Panel 10306
☒ Arthritis Panel ☐ HIV 19728 ☐ Anemia Profile
☐ CT/GC swab/urine 17305 ☐ CT/GC OTV 17618 ☐ HSV (IgM AB r/iter) 7438
☐ KOH (skin, hair, nail) 4605 ☐ KOH (other than s/h/n) 4553
 Culture (Source): _____
 Dr. A: _____ Bill Ins: BC
 Dr. B: ☒ Bill Doctor: 723.1
 724.2 Dr. B. Abraham, P.C.
 10700 Highway 174, Suite 100, Houston, TX 77056

219. As indicated in the pre-printed, hard-copy paper lab requisition above, a provider in Dr. Abraham's practice ordered the "Arthritis Panel" as well as a "CBC" test for Patient X, unaware that a "CBC" test was one of the seven individual tests included in the "Arthritis Panel" created by Quest for the practice. Thus, the provider ordered duplicative "CBC" tests for Patient X. As with other Quest client script pads, there is no indication on the script pad of what the tests are that are included in the "Arthritis Panel" or the "Anemia Panel." Quest knew or recklessly disregarded that given the duplicative order for the same test

individually and as part of a panel, Quest could not truthfully certify that each test in the panel was Reasonable and Necessary. But Quest did so anyway when it billed for each test thereby submitting a false claim for each test in the panel.

220. The Quest phlebotomist's selection of the "Arthritis Panel" in Care360 would trigger individual tests in the panel to be entered into the electronic Care360 requisition and a bar code to be created for placement on the patient's blood specimen tube. Upon entry into Quest's Care360, the following tests were ordered, performed, and billed with regard to Patient X:

- Comprehensive Metabolic Panel with uric acid (CPT 80053, 84550);
- TSH, 3d Generation (CPT 84443);
- T4, Free (CPT 84439);
- Lipid Panel with Reflex to Direct LDL (CPT 80061);
- Vitamin D, 25-Hydroxy, LC/MS/MS (CPT 82306);
- Rheumatoid Factor (CPT 86431);
- Basic Metabolic Panel with EGFR (CPT 80048);
- Anti-Streptolysin O (CPT 86060);
- Anachoice (TM) Screen with Refl to titer, IFA (CPT 86038);
- C-Reactive Protein (CPT 86140);
- Sed Rate by Modified Westergren (CPT 85652); and
- CBC (includes Diff/PLT) (CPT 85025).

221. The following is the Care360 test requisition for Patient X, which demonstrates how the “Arthritis Panel,” designed and created by Quest employee C.D., automatically populates the seven individual tests included in the custom panel into the lab requisition:

| |
|------------------------------------|
| ICD Diagnosis Code(s): 7242, 7231 |
| Reporting Comments: 3sst 2lav 1red |

Profiles/Tests

249 - ANA CHOICE(TM) SCREEN W/REFL TO TITER, IFA [SERUM]
 265 - ANTI-STREPTOLYSIN O [SERUM]
 809 - SED RATE BY MODIFIED WESTERGREN [BLOOD]
 866 - F4, FREE [SERUM]
 899 - TSH, 3RD GENERATION [SERUM]
 905 - URIC ACID [SERUM]
 3259 - DRAW FEE, PSC SPECIMEN [VARIED]
 4418 - RHEUMATOID FACTOR [SERUM]
 4420 - C-REACTIVE PROTEIN [SERUM]
 6399 - CBC (INCLUDES DIFF/PLT) [BLOOD]
 10165 - BASIC METABOLIC PANEL W/EGFR [SERUM]
 10231 - COMPREHENSIVE METABOLIC PANEL W/EGFR [SERUM]
 14852 - LIPID PANEL WITH REFLEX TO DIRECT LDL [SERUM]
 17306 - VITAMIN D, 25-HYDROXY, LC/MS/MS [SERUM]

222. When the specimen for Patient X arrived at the Quest lab on Montreal Circle in Tucker, Georgia, the Quest testing instruments interpreted the bar code and caused each individual test on the electronic requisition, including those automatically populated from the “Arthritis Panel,” to be performed, and communicated with Quest’s billing system to bill for each individual test that was performed.

223. The seven additional tests resulted in approximately \$70.01 per specimen in Medicare reimbursement, as indicated in the chart below:

| CPT Code | Description | Medicare Reimbursement |
|----------|---|------------------------|
| 86431 | Rheumatoid Factor | \$8.13 |
| 80048 | Basic Metabolic Panel with EGFR | \$12.12 |
| 86060 | Anti-Streptolysin O | \$10.02 |
| 86038 | Anachoice (TM) Screen with Refl to titer, IFA | \$17.32 |
| 86140 | C-Reactive Protein | \$7.41 |
| 85652 | Sed Rate by Modified Westergren | \$3.87 |
| 85025 | CBC (includes Diff/PLT) | \$11.14 |

224. As another representative example of false billing, Quest submitted a claim for payment to Medicare on April 7, 2010, for lab services provided to Patient Y on March 29, 2010, based on a provider in Dr. Abraham's practice selecting the "Arthritis Panel." That selection resulting in a Care360 test requisition for the following tests: Rheumatoid Factor (CPT 86431); Basic Metabolic Panel with EGFR (CPT 80048); Anti-Streptolysin O (CPT 86060); Anachoice (TM) Screen with Refl to titer, IFA (CPT 86038); C-Reactive Protein (CPT 86140); Sed Rate by Modified Westergren (CPT 85652); and CBC (includes Diff/PLT) (CPT 85025). Quest billed Medicare in the amount of \$323.28 for these tests and Medicare paid \$70.01.

225. As intended, in the months following Quest's design, creation, and implementation of custom panels for Dr. Abraham's practice, Quest's revenue per

day for lab tests from Dr. Abraham's practice increased from \$244.77 in 2008 to \$2,076.79 in 2009; \$3,535.41 in January 2010; \$4,268.14 in February 2010; \$4,313.51 in March 2010; and \$4,562.42 in April 2010. Hence, the excessive, non-patient specific tests Quest added to Dr. Abraham's "Arthritis Panel" substantially increased Quest's revenue.

226. Relator identified the Dr. Abraham's script pad and the related Quest false claims for payment during her investigation into Quest's scheme to fraudulently increase its revenue from Government payors by having its Clients use Quest-created electronic custom panels in Care 360. Because the Client was in her business unit, Relator could and did require that Dr. Abraham execute a PAF. That PAF was not created or implemented as part of the Quest centralized corporate panel creation process, but only as a stop gap measure taken by Relator as the Compliance Officer for the SE BU. any Quest corporate panel creation without Quest corporate having any knowledge of that PAF. Because she did not discover the problem earlier, this Quest Client used the panels without any PAF for some time.

227. Relator provided the On November 10, 2009, Relator provided another example, that of Patient A of the Quest Client, The Highlands Center for Women, as another example of custom panels being built by Quest employees in Care360 to M.H. and Ms. Wiser for their use in a presentation they were giving to

the Compliance Management Team at Corporate. That Patient A example is set forth below as an illustrative example of Quest's fraudulent conduct hereon.

228. On April 22, 2008, Quest phlebotomist K.S. created and designed a custom profile of tests in Care360, referred to as the "PCOS" panel for Highlands Center for Women, P.A., located at 105 Halton Village Circle, Suite A, Greenville, South Carolina 29607. Quest employee K.S. populated the "PCOS" panel in Care360 with the following sixteen tests:

4021 [ESTRADIOL]

470 [FSH]

746 [PROLACTIN]

899 [TSH, 3RD GENERATION]

615 [LH]

36170 [TESTOSTERONE, FREE AND TOTAL, LC/MS/MS]

10231 [COMPREHENSIVE METABOLIC PANEL W/EGFR]

14852 [LIPID PANEL WITH REFLEX TO DIRECT LDL]

561 [INSULIN]

402 [DHEA SULFATE]

17180 [17 HYDROXYPROGESTERONE, LC/MS/MS]

745 [PROGESTERONE]

8396 [HCG, TOTAL, QN]


482 [GGT]

905 [URIC ACID]

593 [LD]

229. Once the “PCOS” panel was created by Quest employee K.S., it was in place for all providers at Highlands Center for Women indefinitely, and it could be selected on pre-printed, hard-copy script pads for use in Care360’s electronic platform. A redacted copy of the pre-printed, hard-copy paper lab requisition, created by Quest for use at Highlands Center for Women appears below and demonstrates the “PCOS” panel:

*only -
6 hours*

| | | |
|--|--|--|
| Highlands Center for Women Everett P. Fuller, MD, FACOG 135 Commonwealth Drive, Suite 300 Chryel David A. Godwin, MD, FACOG Greenville, SC 29615 Matthew I Brandi K. Alt, DO (864) 675-1190 Sharon E. Laura D. Wieland LeBel, MD, FACOG Jeffie Deborah M. Jenkins, MN, WHNP FACOG | | 28628328  |
|--|--|--|

QUEST Diagnostics
GYN Chemistry Orders
 Account #: 7070568

Collection Date: 3/31/2009

Patient Name: [REDACTED] **Patient's ID#:** [REDACTED]

SSN: [REDACTED] **DOB:** [REDACTED] **SEX:** female

Phone: [REDACTED]

Address: [REDACTED]

Ordering Physician: Laura Wieland Lebel, M.D., F.A.C.O.G.
DEA:

Diagnosis Code: 256.4 PCOS

Test(s) Ordered: PCOS Panel

Other Tests:

Culture Source:

230. As indicated in the pre-printed, hard-copy paper lab requisition above, Dr. Laura Wieland Lebel of the Highlands Center for Women ordered the “PCOS”

panel for Patient A.

231. The Quest phlebotomist's selection of the "PCOS" panel in Care360 would trigger individual tests in the panel to appear in the electronic Care360 requisition and a bar code to be created for placement on the patient's blood specimen tube. Upon selection of this panel in Care360, the following sixteen tests were ordered, performed, and billed with regard to Patient A:

4021 [ESTRADIOL]

470 [FSH]

746 [PROLACTIN]

899 [TSH, 3RD GENERATION]

615 [LH]

36170 [TESTOSTERONE, FREE AND TOTAL, LC/MS/MS]

10231 [COMPREHENSIVE METABOLIC PANEL W/EGFR]

14852 [LIPID PANEL WITH REFLEX TO DIRECT LDL]

561 [INSULIN]

402 [DHEA SULFATE]

17180 [17 HYDROXYPROGESTERONE, LC/MS/MS]

745 [PROGESTERONE]




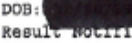



8396 [HCG, TOTAL, QN]

482 [GGT]

905 [URIC ACID]

593 [LD]

232. The following the Care360 electronic requisition for Patient A, which demonstrates how the “PCOS” panel, designed and created by Quest employee K.S., automatically populated the lab requisition with the sixteen individual tests included in the ease of order panel:

| | | | | | |
|--|--|--|--|--|--|
| HIGHLANDS CTR FOR WOMEN, PA GYN ACCOUNT 135 COMMONWEALTH DR STE 300 GREENVILLE, SC 29615-4831 864-675-1190 | |  | | Patient Information  | |
| Collection Date: 04/09/2009 Time: 10:52:00 Urine Volume: Hours: Fasting: Lab Reference ID: | | Pat ID #:  DOB:  Sex: F Result Notification: Normal | | SSN:  Room/LOC: | |
| UPIN: Q22055 LEBEL, LAURA Ref Physician Provider ID: LEBEL, LAURA NPI: 1447211792 SKB-GVL(sgenc01) | | Responsible Party:  Primary Carrier: BCSSC - BLUE CROSS OF S CAROLINA Insurance #: | | Bill Type: Insurance Phone: 8648959955 SSN:  Relation: Self Sex: F | |
| ICD Diagnosis Code(s): 2564 | | | | | |

4584 2 Serum Vials -
400

| Profiles/Tests |
|----------------|
|----------------|

402 - DHEA SULFATE [SERUM]
 470 - FSH [SERUM]
 482 - GGT [SERUM]
 561 - INSULIN [SERUM]
 593 - LD [SERUM]
 615 - LH [SERUM]
 745 - PROGESTERONE [SERUM]
 746 - PROLACTIN [SERUM]
 899 - TSH, 3RD GENERATION [SERUM]
 905 - URIC ACID [SERUM]
 4021 - ESTRADIOL [SERUM]
 8396 - HCG, TOTAL, QN [SERUM]
 10231 - COMPREHENSIVE METABOLIC PANEL W/EGFR [SERUM]
 14852 - LIPID PANEL WITH REFLEX TO DIRECT LDL [SERUM]
 17180 - 17 HYDROXYPROGESTERONE, LC/MS/MS [SERUM]
 36170 - TESTOSTERONE, FREE AND TOTAL, LC/MS/MS [SERUM]

233. When the specimen for Patient A arrived at the Quest lab at 430 Roper Mountain Road in Greenville, South Carolina, the Quest testing instruments interpreted the bar code and caused each individual test on the electronic requisition, including those automatically populated from the “PCOS” panel, to be performed, and communicated with QBS to bill for each individual test that was performed.

234. Upon learning that Quest employees created custom panels in Care360, Relator audited providers in her Southeast business unit, including Alabama, Tennessee, South Carolina, North Carolina, and Georgia. During her audit, she learned that over 3,000 custom panels were created, beginning at least in May 2004.

235. As an example, a Quest employee created a custom panel titled “LPTREAT” for The Medical Group, located at Memphis, Tennessee, on May 28, 2004, which contained the following six tests:

8293 [DIRECT LDL]

823 [ALT]

822 [AST]

234 [ALKALINE PHOSPHATASE]

482 [GGT]

374 [CREATINE KINASE, TOTAL]

236. As an example, a Quest employee created a custom panel titled “12345” for Nashville Fertility Center, located at 345 23rd Avenue N #401, Nashville, Tennessee 37203, on February 8, 2005, which contained the following nine tests:

6399 [CBC (INCLUDES DIFF/PLT)]

799 [RPR (MONITOR) W/REFL TITER]

8472 [HEPATITIS C ANTIBODY]

7600 [LIPID PANEL]

873 [TESTOSTERONE, TOTAL]

899 [TSH]

861 [T-3 UPTAKE]

867 [T-4 (THYROXINE), TOTAL]

927 [VITAMIN B12]

237. As an example, a Quest employee C.D. created a custom panel titled “ED1111” for Lifeboat Medical Associates, located at 1201 Georgian Park, Peachtree City, Georgia 30269, on July 7, 2006, which contained the following nine tests:

6399 [CBC (INCLUDES DIFF/PLT)]

5363 [PSA, TOTAL]

15983 [TESTOSTERONE, TOTAL, LC/MS/MS]

866 [T-4, FREE]

746 [PROLACTIN]

483 [GLUCOSE]

470 [FSH]

7600 [LIPID PANEL]

10231 [COMPREHENSIVE METABOLIC PANEL]

238. Another example of Quests' Care360 ease of order panel fraud is that of a pain management clinic in NC, called, "Cape Fear," that was a Client of Quest. Quest Sales Rep Paige Whittaker created a Care360 ease of order panel that included a screening for certain drugs as well as a confirmation of the existence of those drugs in a patient's urine sample. Cape Fear did its own screenings and thought it was using the Quest Care360 ease of order panel only to confirm the results of positive screenings. But Quest had populated the panel with screenings too. When NC Medicaid audited Cape Fear's bills for screenings, it saw that Quest had conducted the same tests on the same patients and sought to recoup from Cape Fear the reimbursements for all of its screenings.

239. Cape Fear contacted Quest about the NC Medicaid recoupment for the screenings. To keep the Client, Quest reimbursed Cape Fear for the every dollar recouped by NC Medicaid, but did not report its overpayment from Medicaid to Quest or otherwise disclose to Medicaid or Medicare what it knew was an ongoing scheme to bill the Government for all tests in Care360 ease of order panels even though Quest knew it had bypassed every safeguard against billing for medically

necessary tests it had set up for the paper-ordered custom panels.

240. Quest's fraudulent conduct of allowing sales reps and phlebotomists to create ease of order panels in Care360 and then billing for each test in a panel with a false certification that it was medically necessary without any way of knowing if the test was medically necessary commenced at least as early as 2004 and persisted through at least 2016: Quest billed Georgia Medicaid for tests conducted because of their inclusion in Care360 ease of order panels for Georgia Medicaid beneficiaries at least as recently as 2016.

241. Quest's Compliance Officer for Sales and Marketing, J.H., confirmed to Relator in 2009 that when Quest launched Care360 and its ease of order panel functionality back in the early 2000s, Quest management knew it was a massive Compliance risk to do so. Then in 2007, Alternative Care360 was created but not implemented. Then in 2009, Relator found the scheme going strong across the country, raised an alarm but Quest persisted in doing nothing and continued submitting false claims to the Government.

242. On September 16, 2009, when Relator had started uncovering the Care360 scheme and reporting it to her Compliance superiors, she received a voicemail from Quest's Compliance Officer for Sales and Marketing, Karen McKeown, angrily directing her to "cease and desist" all efforts related to investigating the Care360 panels test billing issue and to send all presentations,

emails and other communications used to discuss the issue to Ms. McKeown.

McKeown said she had discussed the matter with VP of Compliance Tim Sharpe and that he was not happy with what Relator was doing and that “we” will get back to you on how to proceed and whether you may proceed.

243. It is Relator’s understanding that Quest’s fraudulent conduct continues to the present day in that she has heard from time to time from other labs that utilize procedures required by CLIA when using electronic panels that Quest seems to have so far gotten away with not using any safeguards.

THE UNITED STATES AND THE STATE OF GEORGIA
WERE HARMED BY QUEST’S CONDUCT

244. As a direct result of Quest’s conduct, federal and state Government payors paid Quest millions of dollars for thousands of false and/or fraudulent claims for services that were not medically necessary. Quest’s deliberate and intentional failure to take steps to ensure that providers intended to order the tests included in the Care360 ease of order panels designed, created, and implemented by Quest employees goes to the essence of the Government’s economic bargain with Quest under the terms of the Government healthcare programs impacted. Had Quest told the Government payors the truth, that Quest did not know whether each test for which it was billing was Reasonable and Necessary, by not submitting the certification required for reimbursement, the Government would not have paid Quest’s claims for each test.

245. Relator is not aware of any information that the Government regularly pays claims for tests that are not Reasonable and Necessary, or that the Government has ever paid a specific claim with knowledge that the laboratory submitting the claim did not know whether the claim was Reasonable and Necessary but falsely certified that it was in order to receive reimbursement.

246. Indeed, the Government has denied claims and has brought enforcement actions in innumerable cases based on lack of medical necessity for testing services and false claims resulting therefrom. *See, e.g., KGV Easy Leasing Corporation v. Sebelius, Sec. of HHS*, 2011 WL 490990 *1 (9th Cir. Feb. 14, 2011) (affirming HHS' determination to deny claims because laboratory service provider failed to demonstrate that tests were medically reasonable and necessary where pre-printed physician order forms, submitted in support of its reimbursement claims, did not conform to the requirements of 42 C.F.R. § 410.33(d), which mandates both that (1) the beneficiary's treating physician order the tests; and (2) the results are used "in the management of the beneficiary's specific medical problem"); *U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487 (D.S.C. 2016) (finding the Government's complaint in intervention sufficiently alleged that "tests . . . submitted to Medicare and TRICARE for reimbursement . . . were false claims because they were not medically necessary tests and Medicare and TRICARE only cover medically necessary

care” and that “[a]ny documentation (that is, any record or statement) that must be submitted to Medicare or TRICARE for reimbursement is material because it has ‘a natural tendency to influence, or be capable of influencing, the Government’s decision to pay’”).

COUNT I
False Claims Act: Presentment of False Claims
31 U.S.C. § 3729(a)(1)(A)

247. Relator incorporates by reference and re-alleges the factual allegations stated in Paragraphs 1 – 246 as if fully set forth herein.

248. As set forth herein, Quest, individually and by and through its agents, officers, and employees, knowingly presented to the United States false or fraudulent claims for payment in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

249. Quest knowingly submitted false or fraudulent claims for laboratory testing services with false certifications that the services were eligible for reimbursement as medically necessary, when in fact Quest had intentionally not implemented procedures that would have allowed it to know whether its required certification was truthful.

250. Said claims were presented with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

251. The United States, unaware of the falsity of the claims submitted or

caused to be submitted by Quest and in reliance on the accuracy thereof, paid Quest for such false or fraudulent claims that it otherwise would not have paid.

252. By reasons of the acts and conduct of Quest in violation of 31 U.S.C. § 3729(a)(1)(A), the United States has suffered actual damages in an amount to be proven at trial.

253. By virtue of these false claims, Quest is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the False Claims Act.

WHEREFORE, Relator, on behalf of the United States, demands judgment against Quest, ordering that:

1. Pursuant to 31 U.S.C. § 3729(a), Quest pay an amount equal to three times the amount of damages the United States has sustained because of Quest's fraudulent conduct, plus a civil penalty of at least \$5,500 and up to \$25,076 or such other penalty as the law may permit and/or require for each violation of 31 U.S.C. § 3729 *et seq.*;
2. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3729(d) of the False Claims Act and/or any other applicable provision of law;

3. Relator be awarded all costs and expenses of this action, including attorneys' fees as provided by 31 U.S.C. § 3730(d) and any other applicable provision of the law;
4. Relator be awarded pre- and post-judgment interest on the awards ordered herein; and
5. Relator be awarded such other and further relief as the Court may deem to be just and proper.

COUNT II

False Claims Act: Making and Using False Records or Statements 31 U.S.C. § 3729(a)(1)(B)

254. Relator incorporates by reference and re-alleges the factual allegations stated in Paragraphs 1 – 246 as if fully set forth herein.

255. As set forth herein, Quest, individually and by and through its agents, officers, and employees, knowingly made, used, or caused to be made or used, false statements—including, but not limited to, false statements on forms CMS-855B, 837P and CMS-1500—material to numerous false and fraudulent claims (and the Government's decision to pay) in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

256. The United States, unaware of the falsity of the statements made by Defendant Quest and in reliance on the accuracy thereof, paid monies to Quest that it would not otherwise have been obligated to pay.

257. By reasons of the acts and conduct of Quest in violation of 31 U.S.C. § 3729(a)(1)(B), the United States has suffered actual damages in an amount to be proven at trial.

258. Quest is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil monetary penalties for each false claim. WHEREFORE, Relator, on behalf of the United States, demands judgment against Quest, ordering that:

1. Pursuant to 31 U.S.C. § 3729(a), Quest pay an amount equal to three times the amount of damages the United States has sustained because of Quest's fraudulent conduct, plus a civil penalty of at least \$5,500 and up to \$25,076 or such other penalty as the law may permit and/or require for each violation of 31 U.S.C. § 3729 *et seq.*;
2. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3729(d) of the False Claims Act and/or any other applicable provision of law;
3. Relator be awarded all costs and expenses of this action, including attorneys' fees as provided by 31 U.S.C. § 3730(d) and any other applicable provision of the law;
4. Relator be awarded pre- and post-judgment interest on the awards ordered herein; and

5. Relator be awarded such other and further relief as the Court may deem to be just and proper.

COUNT III

False Claims Act: Concealing and Avoiding Repayment due the Government 31 U.S.C. § 3729(a)(1)(G)

259. Relator incorporates by reference and re-alleges the factual allegations stated in Paragraphs 1 – 246 as if fully set forth herein.

260. As set forth herein, Quest knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the United States in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

261. Quest retained improperly obtained payments, which arose from its submission of false or fraudulent claims for non-patient-specific, non-medically-necessary tests in Care360's ease of order panels from the United States and knowingly concealed and improperly avoided its obligation to repay the improperly obtained payments.

262. By reasons of the acts and conduct of Quest in violation of 31 U.S.C. § 3729(a)(1)(G), the United States has suffered actual damages in an amount to be proven at trial.

263. By virtue of these false claims, Quest is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for

each violation of the Act.

WHEREFORE, Relator, on behalf of the United States, demands judgment against Quest, ordering that:

1. Pursuant to 31 U.S.C. § 3729(a), Quest pay an amount equal to three times the amount of damages the United States has sustained because of Quest's fraudulent conduct, plus a civil penalty of at least \$5,500 and up to \$25,076 or such other penalty as the law may permit and/or require for each violation of 31 U.S.C. § 3729 *et seq.*;
2. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3729(d) of the False Claims Act and/or any other applicable provision of law;
3. Relator be awarded all costs and expenses of this action, including attorneys' fees as provided by 31 U.S.C. § 3730(d) and any other applicable provision of the law;
4. Relator be awarded pre- and post-judgment interest on the awards ordered herein; and
5. Relator be awarded such other and further relief as the Court may deem to be just and proper.

COUNT IV
Georgia FMCA and Georgia Medical Assistance Act:
Presentation of False Claims
O.C.G.A. §§ 49-4-168.1(a)(1), 49-4-146.1(b)

264. Relator incorporates by reference and re-alleges the factual allegations stated in Paragraphs 1 – 246 as if fully set forth herein.

265. As set forth herein, Quest, individually and by and through its agents, officers, and employees, knowingly presented or caused to be presented to the Georgia Medicaid program false or fraudulent claims for payment or approval in violation of the Georgia FMCA, O.C.G.A. § 49-4-168.1(a)(1), and the Georgia Medical Assistance Act, O.C.G.A. § 49-4-146.1(b).

266. Quest knowingly submitted false or fraudulent claims for laboratory testing services with false certifications that the services were eligible for reimbursement as medically necessary, when in fact Quest had intentionally not implemented procedures that would have allowed it to know whether its required certification was truthful.

267. Said claims were presented with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

268. The State of Georgia, unaware of the falsity of the claims submitted or caused to be submitted by Quest and in reliance on the accuracy thereof, paid Quest for such false or fraudulent claims that it otherwise would not have paid.

269. As a direct and proximate result of the false or fraudulent claims Quest knowingly presented or caused to be presented, the State of Georgia has suffered actual damages in an amount to be determined at trial and is entitled to

damages plus a civil penalty in the amount of three times the amount of any excess benefit or payment, plus a civil penalty for each false claim presented.

WHEREFORE, Relator, on behalf of the State of Georgia, demands judgment against Quest, ordering that:

1. Pursuant to O.C.G.A. §§ 49-4-168.1(a) and 49-4-146.1, Quest pay an amount equal to three times the amount of damages the State of Georgia has sustained because of Quest's fraudulent conduct, plus a civil penalty of at least \$5,500 and up to \$25,076 or such other penalty as the law may permit and/or require for each violation of O.C.G.A. §§ 49-4-168.1(a) *et seq.* and 49-4-146.1;
2. Relator be awarded the maximum amount of a relator's share pursuant to the Georgia FMCA, the Georgia Medical Assistance Act, and/or any other applicable provision of law;
3. Relator be awarded all costs and expenses of this action, including attorneys' fees;
4. Relator be awarded pre- and post-judgment interest on the awards ordered herein; and
5. Relator be awarded such other and further relief as the Court may deem to be just and proper.

COUNT V
Georgia FMCA and Georgia Medical Assistance Act:
Making and Using False Records or Statements
O.C.G.A. §§ 49-4-168.1(a)(2), 49-4-146.1(b)

270. Relator incorporates by reference and re-alleges the factual allegations stated in Paragraphs 1 – 246 as if fully set forth herein.

271. Quest knowingly made or used false statements material to false or fraudulent claims paid or approved by the State of Georgia, in violation of O.C.G.A. §§ 49-4-168.1(a)(2) and 49-4-146.1(b). The false statements were Quest's false certifications of eligibility for reimbursement by the Georgia Medicaid program. Quest certified to the Georgia Medicaid program that it would comply with state and federal laws, and the materiality of these violations to the payment of claims are demonstrated by the certifications of compliance in the Statement of Participation, the Electronic Claims Transfer agreement, the Power of Attorney for Electronic Claims Submission, and the relevant Medicaid manuals.

272. If the State of Georgia had known of the falsity of Quest's certifications and representations of full compliance, it would not have paid the claims.

273. As a direct and proximate result of the false or fraudulent records Quest knowingly created and used, the State of Georgia has suffered actual damages in an amount to be determined at trial and is entitled to damages plus a civil penalty in the amount of three times the amount of any excess benefit or

payment, plus a civil penalty for each false claim presented.

WHEREFORE, Relator, on behalf of the State of Georgia, demands judgment against Quest, ordering that:

1. Pursuant to O.C.G.A. §§ 49-4-168.1(a) and 49-4-146.1, Quest pay an amount equal to three times the amount of damages the State of Georgia has sustained because of Quest's fraudulent conduct, plus a civil penalty of at least \$5,500 and up to \$25,076 or such other penalty as the law may permit and/or require for each violation of O.C.G.A. §§ 49-4-168.1(a) *et seq.* and 49-4-146.1;
2. Relator be awarded the maximum amount of a relator's share pursuant to the Georgia FMCA, the Georgia Medical Assistance Act, and/or any other applicable provision of law;
3. Relator be awarded all costs and expenses of this action, including attorneys' fees;
4. Relator be awarded pre- and post-judgment interest on the awards ordered herein; and
5. Relator be awarded such other and further relief as the Court may deem to be just and proper.

COUNT VI

**Georgia FMCA and Georgia Medical Assistance Act:
Concealing and Avoiding Repayment due the Government
O.C.G.A. §§ 49-4-168.1(a)(7), 49-4-146.1(b)**

274. Relator incorporates by reference and re-alleges the factual allegations stated in Paragraphs 1 – 246 as if fully set forth herein.

275. As set forth herein, Quest knowingly concealed or knowingly or improperly avoided or decreased an obligation to pay or transmit property or money to the Georgia Medicaid program. O.C.G.A. §§ 49-4-168.1(a)(7), 49-4-146.1.

276. Quest wrongfully encouraged the overutilization of and ordering of medically unnecessary testing, in knowing violation of material conditions of payment of the Georgia Medicaid program. Quest's actions, if known, would have affected the State of Georgia's decision to pay the resulting claims.

277. Quest had an obligation to repay monies for claims submitted that were not medically necessary.

278. Quest failed to repay this money obligation to the Georgia Medicaid program.

279. As a direct and proximate result of the money obligation Quest concealed and avoided, the State of Georgia has suffered actual damages in an amount to be determined at trial and is entitled to damages plus a civil penalty in the amount of three times the amount of any excess benefit or payment, plus a civil penalty for each false claim presented.

WHEREFORE, Relator, on behalf of the State of Georgia, demands judgment against Quest, ordering that:

1. Pursuant to O.C.G.A. §§ 49-4-168.1(a) and 49-4-146.1, Quest pay an amount equal to three times the amount of damages the State of Georgia has sustained because of Quest's fraudulent conduct, plus a civil penalty of at least \$5,500 and up to \$25,076 or such other penalty as the law may permit and/or require for each violation of O.C.G.A. §§ 49-4-168.1(a) *et seq.* and 49-4-146.1;
2. Relator be awarded the maximum amount of a relator's share pursuant to the Georgia FMCA, the Georgia Medical Assistance Act, and/or any other applicable provision of law;
3. Relator be awarded all costs and expenses of this action, including attorneys' fees;
4. Relator be awarded pre- and post-judgment interest on the awards ordered herein; and
5. Relator be awarded such other and further relief as the Court may deem to be just and proper.

DEMAND FOR JURY TRIAL

Relator respectfully demands a trial by jury on all issues so triable.

Respectfully submitted, this 5th day of October, 2022.

/s/ Michael J. Moore

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CERTIFICATE OF SERVICE AND COMPLIANCE

I hereby certify that on October 5, 2022, I electronically filed the foregoing document, which was prepared in accordance with L.R. 7.1 using Times New Roman, 14-point font, with the Clerk of Court using the CM/ECF system, which will automatically send email notification of such filing to all counsel of record.

/s/ Michael J. Moore

Michael J. Moore